



US009072896B2

(12) **United States Patent**  
**Dar et al.**

(10) **Patent No.:** **US 9,072,896 B2**  
(45) **Date of Patent:** **Jul. 7, 2015**

(54) **SYSTEM FOR TRANSMITTING  
ELECTRICAL CURRENT TO A BODILY  
TISSUE**

(75) Inventors: **Amit Dar**, Kfar Hess (IL); **Shai  
Feldman**, Kfar Saba (IL); **Arkady  
Glukhovsky**, Valencia, CA (US);  
**Shmuel Springer**, Modi'in (IL); **Einan  
Regev**, Kefar Vradim (IL)

(73) Assignee: **Bioness Inc.**, Valencia, CA (US)

(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 262 days.

(21) Appl. No.: **13/513,318**

(22) PCT Filed: **Dec. 1, 2010**

(86) PCT No.: **PCT/US2010/058525**

§ 371 (c)(1),  
(2), (4) Date: **Aug. 8, 2012**

(87) PCT Pub. No.: **WO2011/068849**

PCT Pub. Date: **Jun. 9, 2011**

(65) **Prior Publication Data**

US 2013/0138164 A1 May 30, 2013

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 12/628,273,  
filed on Dec. 1, 2009, now Pat. No. 8,738,137, which is  
a continuation-in-part of application No. 12/197,849,  
filed on Aug. 25, 2008, now Pat. No. 8,467,880.

(60) Provisional application No. 60/957,592, filed on Aug.  
23, 2007.

(51) **Int. Cl.**  
**A61N 1/00** (2006.01)  
**A61N 1/36** (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ..... **A61N 1/36** (2013.01); **A61N 1/0456**  
(2013.01); **A61N 1/048** (2013.01); **A61N**  
**1/0492** (2013.01);

(Continued)

(58) **Field of Classification Search**

USPC ..... 607/2, 46, 152  
See application file for complete search history.

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

3,835,864 A 9/1974 Rasor et al.  
4,032,860 A 6/1977 LeVeen

(Continued)

**FOREIGN PATENT DOCUMENTS**

DE 4331945 3/1995  
JP 62-270173 11/1987

(Continued)

**OTHER PUBLICATIONS**

Office Action for U.S. Appl. No. 11/867,454, mailed Mar. 2, 2011.

(Continued)

*Primary Examiner* — Christopher D Koharski

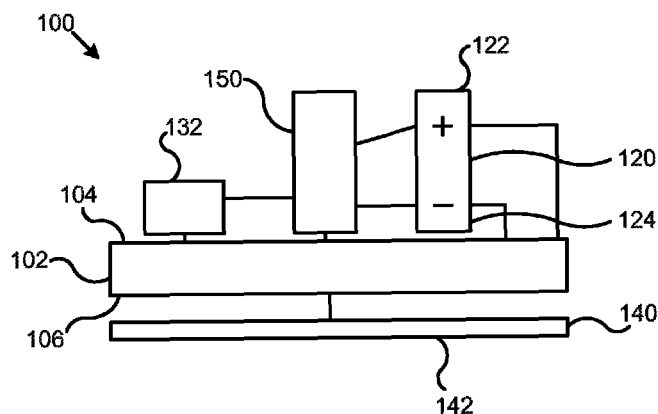
*Assistant Examiner* — Nadia A Mahmood

(74) *Attorney, Agent, or Firm* — Cooley LLP

(57) **ABSTRACT**

In some embodiments, an apparatus includes a substantially rigid base and a flexible substrate. The substantially rigid base has a first protrusion and a second protrusion, and is configured to be coupled to an electronic device. The flexible substrate has a first surface and a second surface, and includes an electrical circuit configured to electronically couple the electronic device to at least one of an electrode a battery, or an antenna. The flexible substrate is coupled to the base such that a first portion of the second surface is in contact with the first protrusion. A second portion of the second surface is non-parallel to the first portion.

**20 Claims, 25 Drawing Sheets**



- (51) **Int. Cl.**  
*A61N 1/04* (2006.01)  
*A61N 1/375* (2006.01)  
*A61N 1/362* (2006.01)
- (52) **U.S. Cl.**  
 CPC ..... *A61N 1/36021* (2013.01); *A61N 1/375*  
 (2013.01); *A61N 1/04* (2013.01); *A61N 1/0472*  
 (2013.01); *A61N 1/36017* (2013.01); *A61N*  
*1/3625* (2013.01); *A61N 1/3756* (2013.01);  
*A61N 1/3758* (2013.01)

(56) **References Cited**

## U.S. PATENT DOCUMENTS

4,088,141 A 5/1978 Niemi  
 4,102,344 A 7/1978 Conway et al.  
 4,323,999 A 4/1982 Yoshizawa et al.  
 4,419,995 A 12/1983 Hochmair et al.  
 4,699,143 A 10/1987 Dufresne et al.  
 4,702,732 A 10/1987 Powers et al.  
 4,832,032 A 5/1989 Schneider  
 5,080,099 A 1/1992 Way et al.  
 5,097,833 A 3/1992 Campos  
 5,169,384 A 12/1992 Bosniak et al.  
 5,246,418 A 9/1993 Haynes et al.  
 5,325,870 A 7/1994 Kroll et al.  
 5,330,516 A 7/1994 Nathan  
 5,337,748 A 8/1994 McAdams et al.  
 5,356,428 A 10/1994 Way  
 5,387,189 A 2/1995 Gory et al.  
 5,397,338 A 3/1995 Grey et al.  
 5,465,715 A 11/1995 Lyons  
 5,487,759 A 1/1996 Bastyr et al.  
 5,514,165 A 5/1996 Malaugh et al.  
 5,531,782 A 7/1996 Kroll et al.  
 5,545,191 A 8/1996 Mann et al.  
 5,562,707 A 10/1996 Prochazka et al.  
 5,578,065 A 11/1996 Hattori et al.  
 5,613,943 A 3/1997 Palumbo  
 5,674,261 A 10/1997 Smith  
 5,766,231 A 6/1998 Erickson et al.  
 5,807,397 A 9/1998 Barreras  
 5,814,090 A 9/1998 Latterell et al.  
 5,879,322 A 3/1999 Lattin et al.  
 5,916,244 A 6/1999 Walters  
 5,948,006 A 9/1999 Mann  
 6,002,965 A 12/1999 Katz et al.  
 6,073,050 A 6/2000 Griffith  
 6,214,032 B1 4/2001 Loeb et al.  
 6,282,448 B1 8/2001 Katz et al.  
 6,366,814 B1 4/2002 Boveja et al.  
 6,377,848 B1 4/2002 Garde et al.  
 6,438,428 B1 8/2002 Axelgaard et al.  
 6,445,955 B1 \* 9/2002 Michelson et al. .... 607/46  
 6,564,102 B1 5/2003 Boveja  
 6,607,500 B2 8/2003 Da Silva et al.  
 6,629,968 B1 10/2003 Jain et al.  
 6,635,045 B2 10/2003 Keusch et al.  
 6,668,191 B1 12/2003 Boveja  
 6,735,474 B1 5/2004 Loeb et al.  
 6,735,475 B1 5/2004 Whitehurst et al.  
 6,754,472 B1 6/2004 Williams et al.  
 6,788,979 B1 9/2004 Axelgaard et al.  
 6,840,919 B1 1/2005 Håkansson  
 6,879,859 B1 4/2005 Boveja  
 6,892,098 B2 5/2005 Ayal et al.  
 6,896,675 B2 5/2005 Leung et al.  
 6,928,320 B2 8/2005 King  
 6,941,171 B2 9/2005 Mann et al.  
 6,961,623 B2 11/2005 Prochazka  
 6,997,735 B2 2/2006 Ehr et al.  
 7,013,179 B2 3/2006 Carter et al.  
 7,047,071 B2 5/2006 Wagner et al.  
 7,096,064 B2 8/2006 Deno et al.  
 7,146,210 B2 12/2006 Palti  
 7,242,982 B2 7/2007 Singhal et al.

7,324,853 B2 1/2008 Ayal et al.  
 7,389,145 B2 6/2008 Kilgore et al.  
 7,502,652 B2 3/2009 Gaunt et al.  
 7,536,226 B2 5/2009 Williams et al.  
 8,332,029 B2 12/2012 Glukhovsky et al.  
 8,406,886 B2 3/2013 Gaunt  
 8,467,880 B2 6/2013 Glukhovsky et al.  
 8,538,517 B2 9/2013 Glukhovsky et al.  
 8,738,137 B2 5/2014 Dar et al.  
 2002/0019652 A1 2/2002 Da Silva et al.  
 2002/0055761 A1 5/2002 Mann et al.  
 2002/0058982 A1 5/2002 Axelgaard et al.  
 2002/0151951 A1 10/2002 Axelgaard et al.  
 2002/0193844 A1 12/2002 Michelson et al.  
 2003/0028232 A1 2/2003 Camps et al.  
 2003/0078642 A1 4/2003 Malaney et al.  
 2003/0139794 A1 7/2003 Jenney et al.  
 2003/0171792 A1 9/2003 Zarinetchi et al.  
 2003/0181090 A1 9/2003 Ehr et al.  
 2003/0199807 A1 10/2003 Dent et al.  
 2003/0212395 A1 11/2003 Woloszko et al.  
 2003/0212440 A1 11/2003 Boveja  
 2004/0130455 A1 7/2004 Prochazka  
 2004/0176804 A1 9/2004 Palti  
 2004/0199222 A1 10/2004 Sun et al.  
 2004/0204686 A1 10/2004 Porter et al.  
 2004/0220641 A1 11/2004 Wagner et al.  
 2004/0267333 A1 12/2004 Kronberg  
 2005/0070970 A1 3/2005 Knudson et al.  
 2005/0136385 A1 6/2005 Mann et al.  
 2005/0165461 A1 7/2005 Takeda et al.  
 2005/0277841 A1 12/2005 Shennib  
 2006/0064140 A1 3/2006 Whitehurst et al.  
 2006/0206165 A1 9/2006 Jaax et al.  
 2006/0271118 A1 11/2006 Libbus et al.  
 2007/0060975 A1 3/2007 Mannheimer et al.  
 2007/0088419 A1 4/2007 Fiorina et al.  
 2008/0004676 A1 1/2008 Osypka et al.  
 2008/0033510 A1 2/2008 Herregraven et al.  
 2008/0046053 A1 2/2008 Wagner et al.  
 2008/0243216 A1 10/2008 Zilberman et al.  
 2008/0288026 A1 11/2008 Cross et al.  
 2009/0054952 A1 2/2009 Glukhovsky et al.  
 2009/0177131 A1 7/2009 Dar et al.  
 2009/0326602 A1 12/2009 Glukhovsky et al.  
 2010/0016929 A1 1/2010 Prochazka  
 2010/0076533 A1 3/2010 Dar et al.  
 2011/0282412 A1 11/2011 Glukhovsky et al.  
 2014/0316497 A1 10/2014 Gaunt et al.

## FOREIGN PATENT DOCUMENTS

JP 63-317164 12/1988  
 JP 2-234774 9/1990  
 JP 2006-074151 10/1994  
 JP 8-66842 3/1996  
 JP 9-66110 3/1997  
 JP 2002-517293 6/2002  
 JP 2003-501207 1/2003  
 JP 2003-512139 4/2003  
 JP 2004-501727 1/2004  
 JP 2005-237941 9/2005  
 JP 2009-10003 1/2009  
 WO WO 95/10323 4/1995  
 WO WO 01/03768 1/2001  
 WO WO 02/02182 1/2002  
 WO WO 2005/011541 2/2005  
 WO WO 2005/070494 8/2005  
 WO WO 2006/101917 9/2006  
 WO WO 2006/113654 10/2006  
 WO WO 2006/113801 10/2006  
 WO WO 2007/02741 1/2007  
 WO WO 2008/140242 11/2008

(56)

**References Cited**

## FOREIGN PATENT DOCUMENTS

WO	WO 2009/058258	5/2009
WO	WO 2011/068849	6/2011

## OTHER PUBLICATIONS

Supplementary Search Report for European Patent Application No. 08827776.9, mailed Mar. 10, 2011.

Notice of Reasons for Rejection for Japanese Application No. 2010-522104, mailed Feb. 12, 2013.

Office Action for U.S. Appl. No. 12/197,849, mailed Sep. 23, 2011.

Office Action for U.S. Appl. No. 12/197,849, mailed Feb. 13, 2012.

Office Action for U.S. Appl. No. 12/197,849, mailed May 10, 2012.

Office Action for U.S. Appl. No. 12/197,849, mailed Sep. 17, 2012.

International Search Report and Written Opinion for International Application No. PCT/US2008/074254, mailed Nov. 3, 2008.

Office Action for Australian Application No. 2010326076, dated Jul. 8, 2013.

Supplementary European Search Report for European Application No. 10835039, Dec. 13, 2013.

Office Action for Japanese Application No. 2012-542152, mailed Mar. 14, 2014.

Office Action for U.S. Appl. No. 12/628,273, mailed Jan. 24, 2012.

Office Action for U.S. Appl. No. 12/628,273, mailed May 30, 2012.

Office Action for U.S. Appl. No. 12/628,273, mailed Oct. 1, 2012.

Office Action for U.S. Appl. No. 12/628,273, mailed Jun. 14, 2013.

International Search Report and Written Opinion for International Application No. PCT/US10/58525, mailed Feb. 7, 2011.

Office Action for U.S. Appl. No. 12/400,202, mailed Mar. 5, 2012.

Office Action for U.S. Appl. No. 12/400,202, mailed Aug. 8, 2012.

Gans, L. et al., "The Stimulus Router: A Novel Means of Directing Current From Surface Electrodes to Nerves," 10th Annual Conference of the International FES Society (Jul. 2005), Montreal, Canada, pp. 21-23.

Lee, C., "Scientists create paper-thin, flexible, biodegradable battery," [online] [Retrieved on Jun. 20, 2008] Retrieved from the Internet: <URL: <http://arstechnica.com/news.ars/post/20070813-scientists-create-paper-thin-flexible-biodegradable-battery.html>>.

Prochazka, A., "Neural Prosthesis Program Meeting," NIH Meeting, Nov. 2004, 5 pages.

Solo Instructions for Use, Shire, Moat Farm, Case Lane Five Ways, Hatton, Warks, CV35 7JD—Issued Mar. 9, 2000, 6 pages.

Office Action for Canadian Application No. 2,697,381, mailed Dec. 9, 2014.

\* cited by examiner

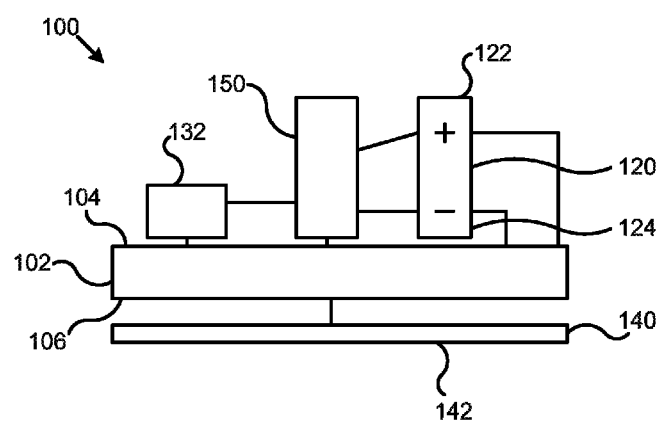


FIG. 1

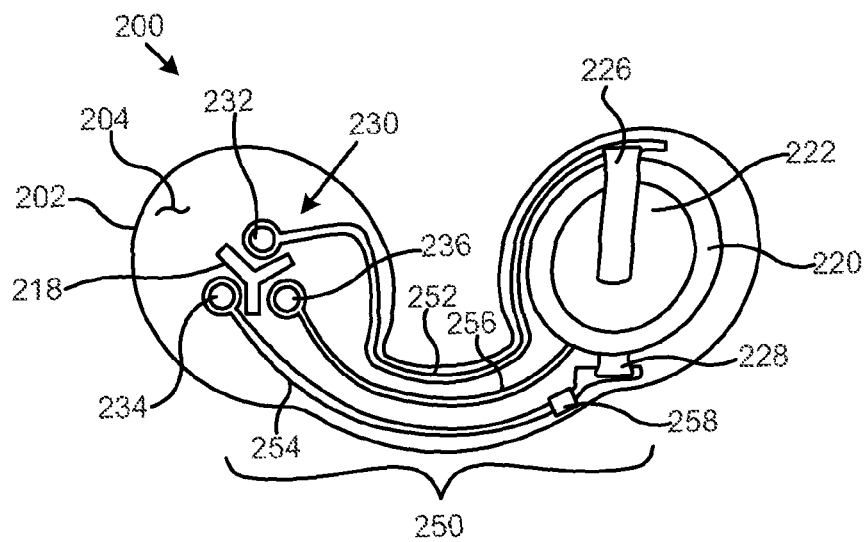


FIG. 2

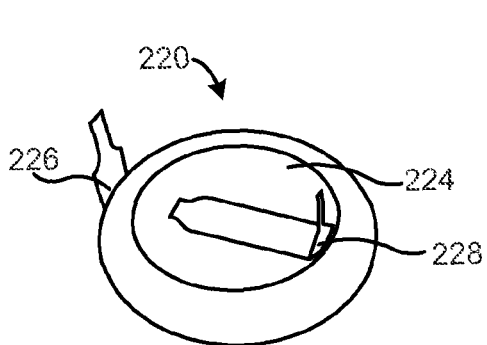


FIG. 3A

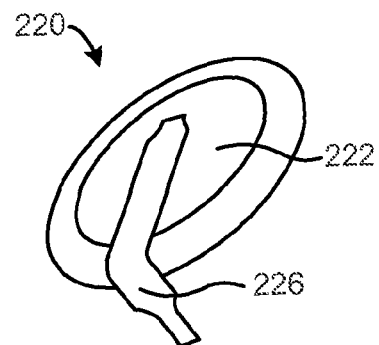


FIG. 3B

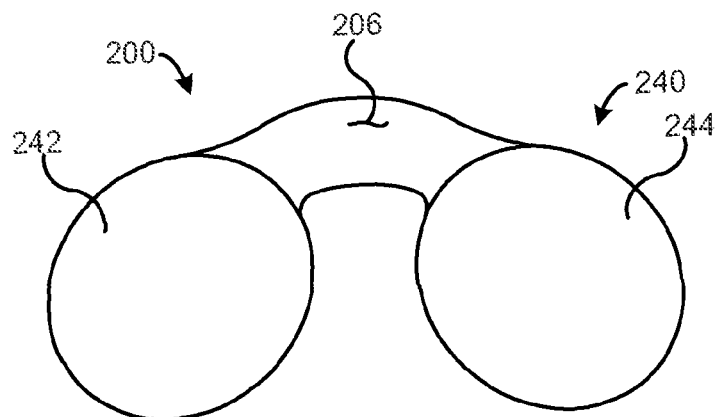


FIG. 4

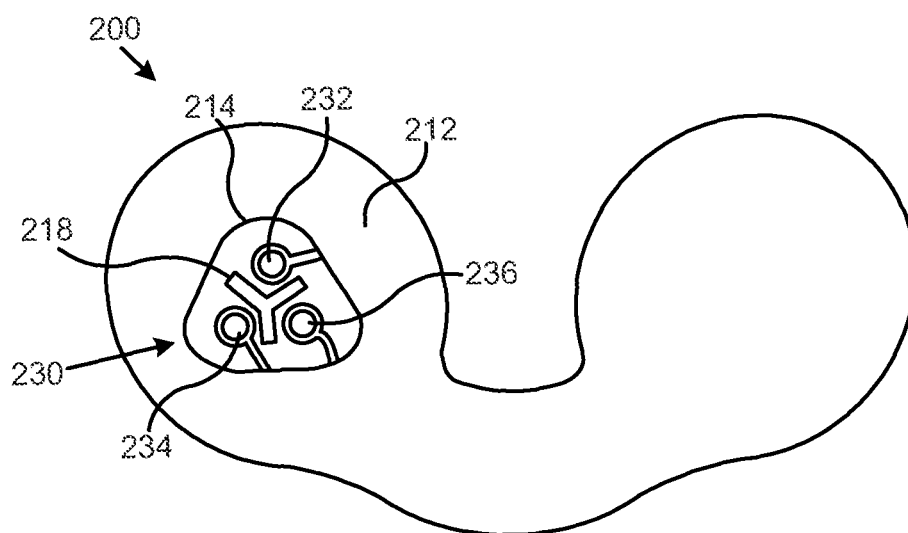


FIG. 5

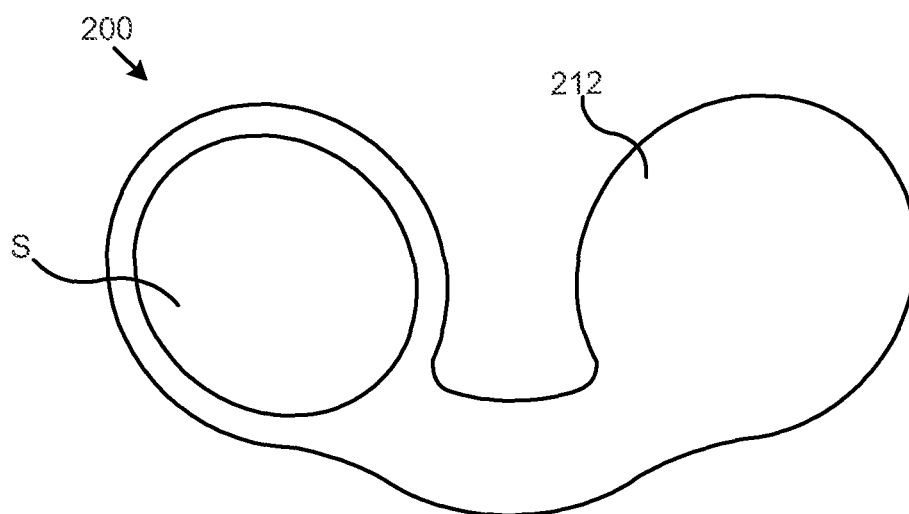


FIG. 6

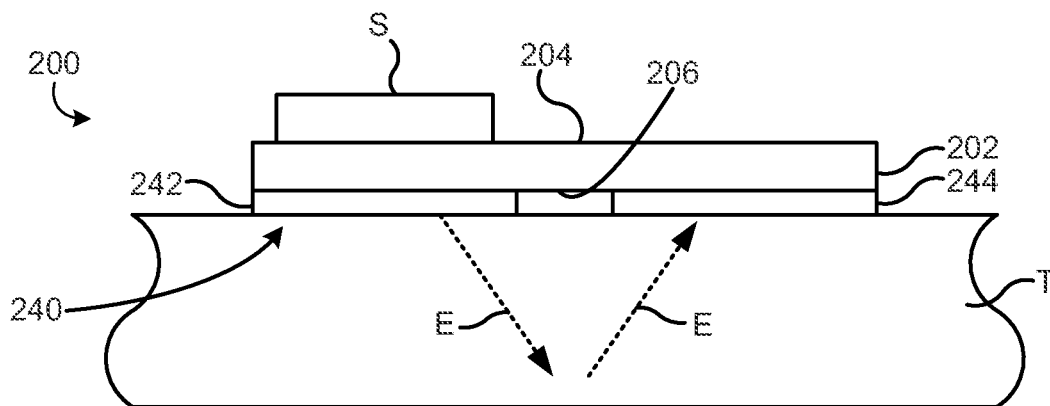


FIG. 7

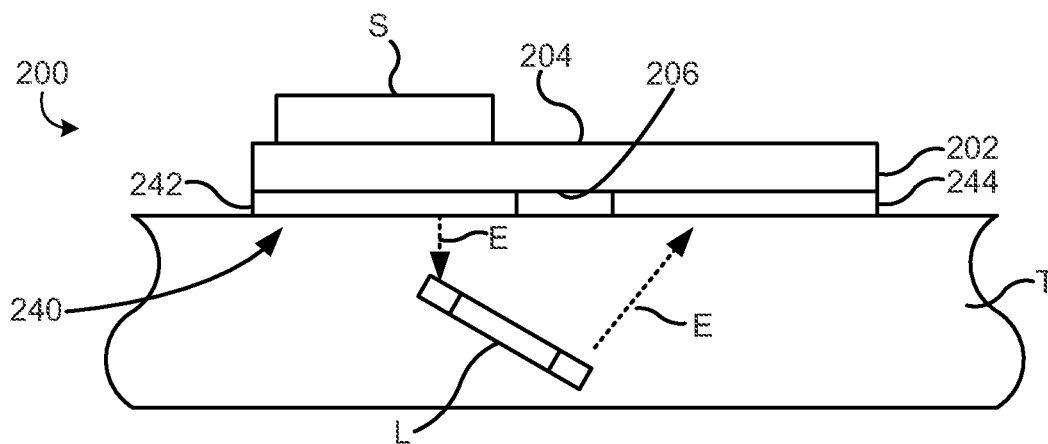


FIG. 8

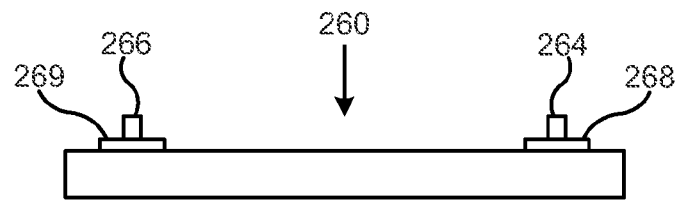


FIG. 9A

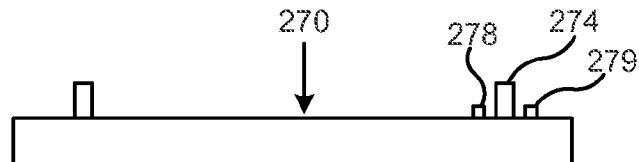


FIG. 9B

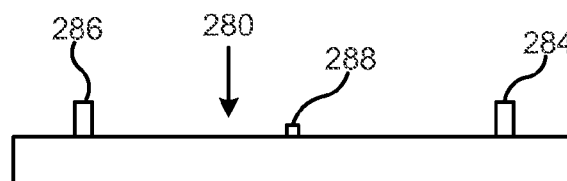


FIG. 9C

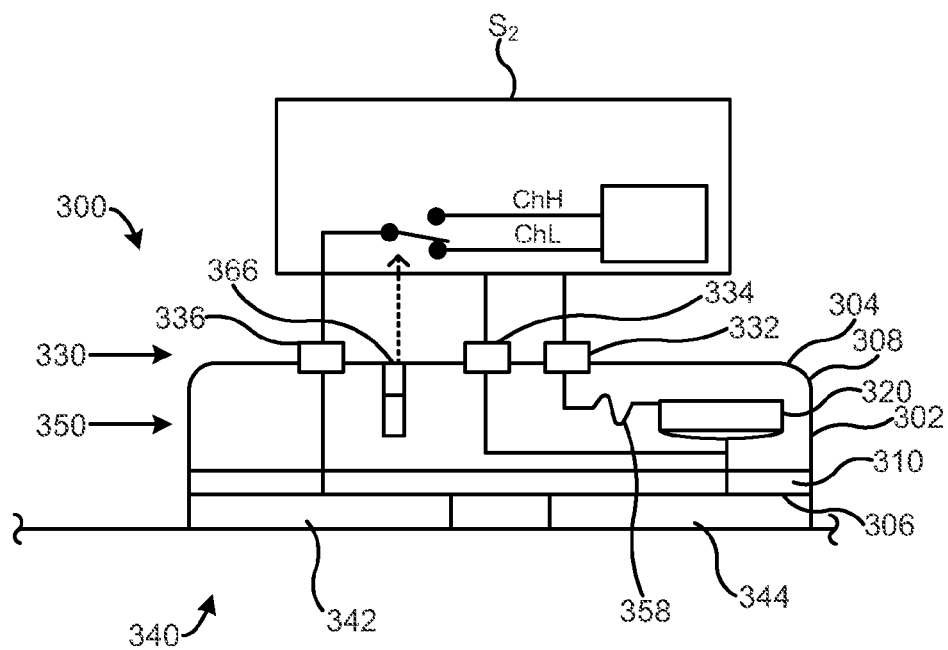


FIG. 10



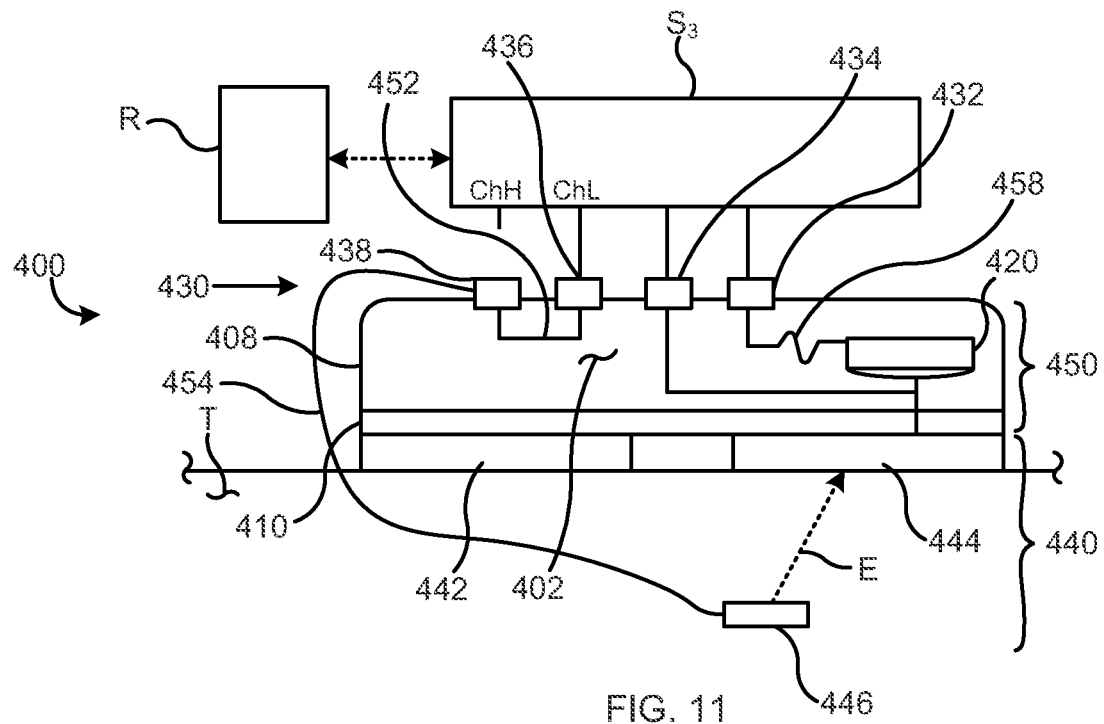


FIG. 11

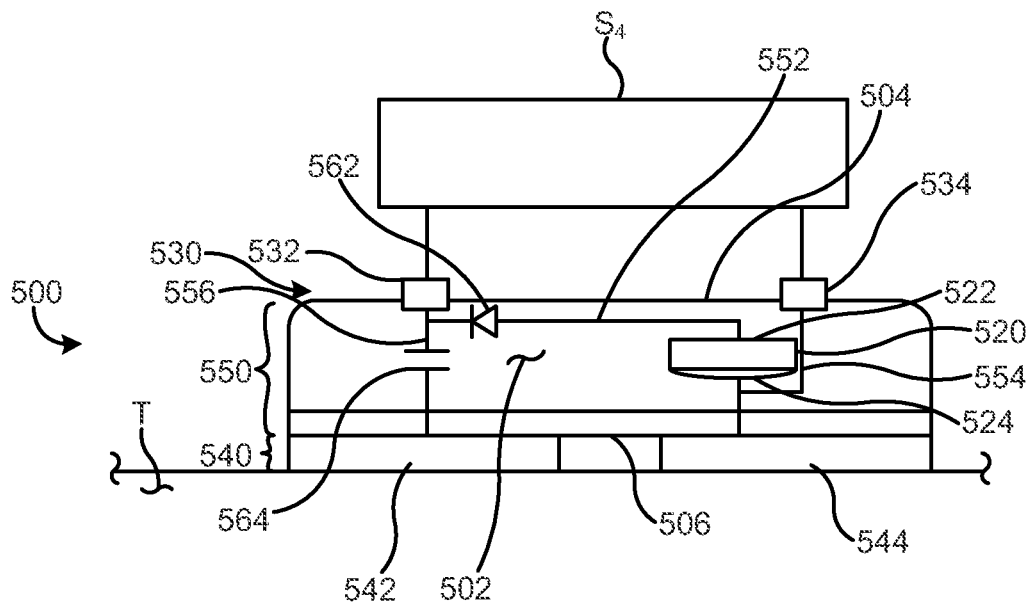


FIG. 12

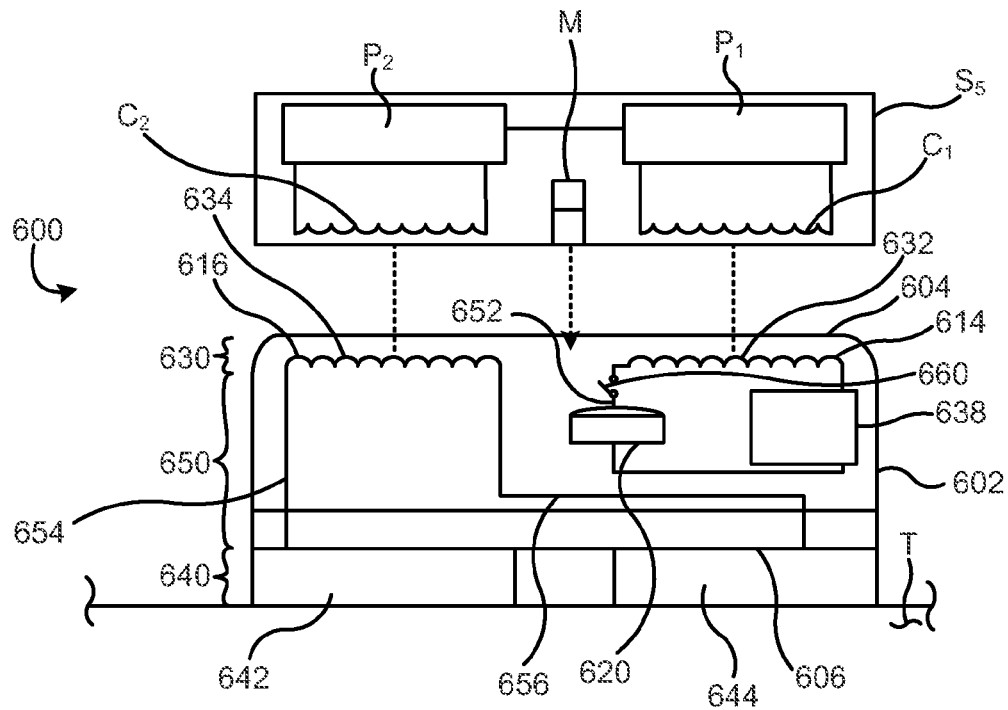


FIG. 13

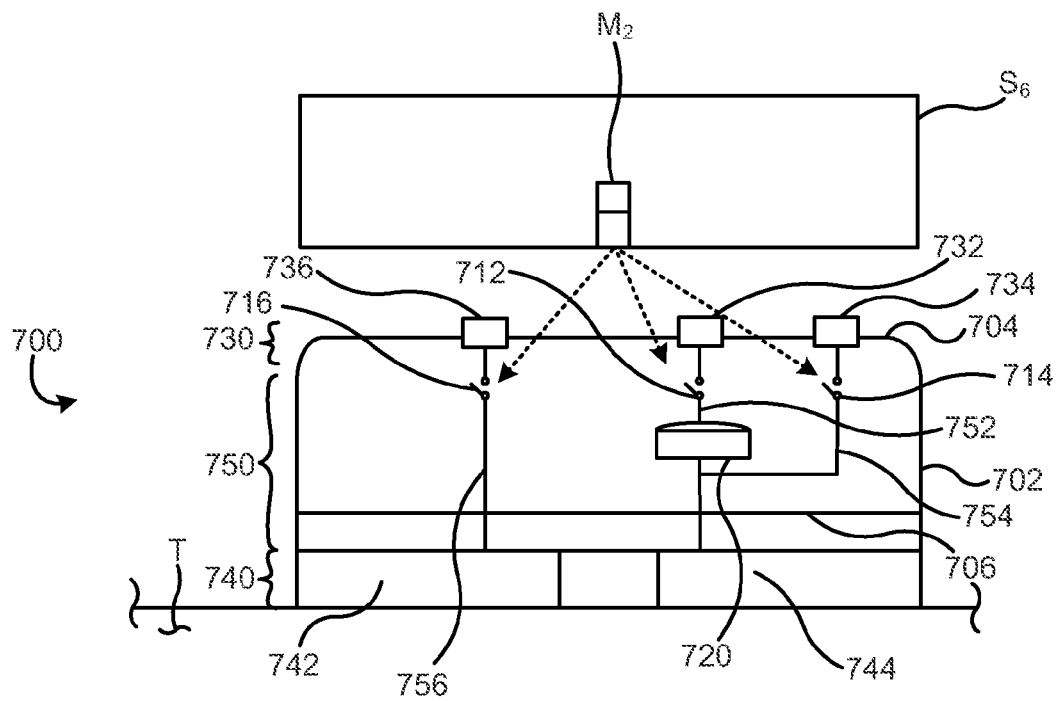


FIG. 14

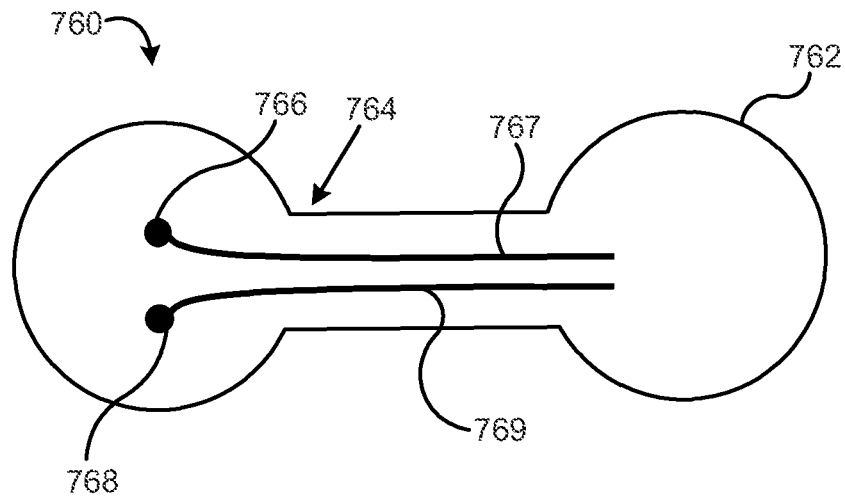


FIG. 15

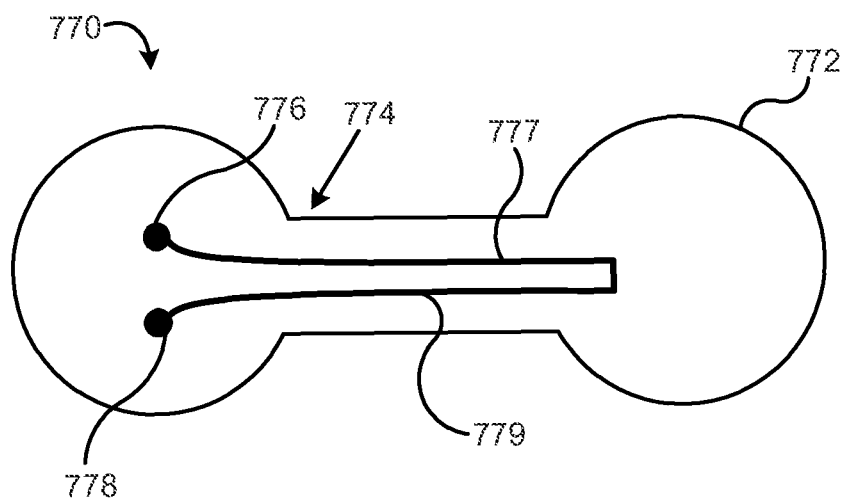


FIG. 16

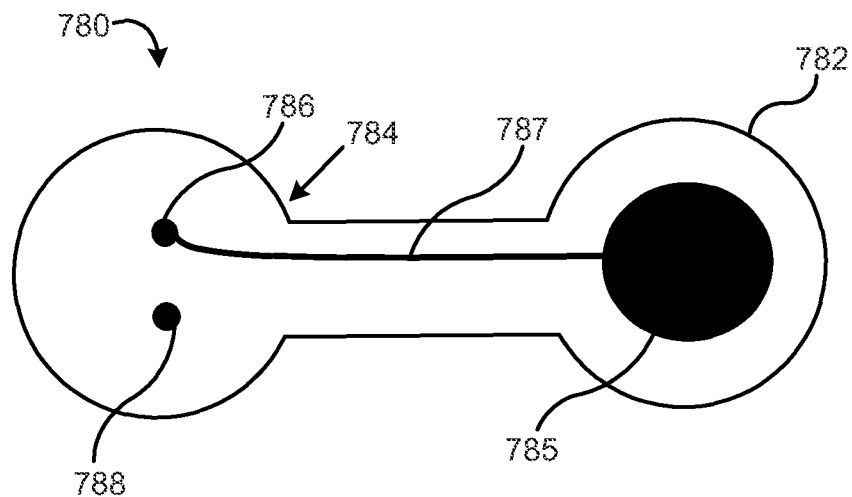


FIG. 17

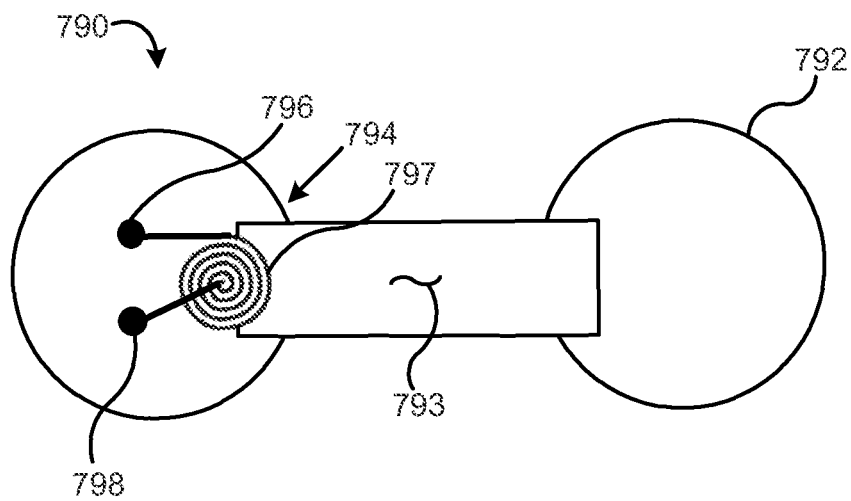


FIG. 18

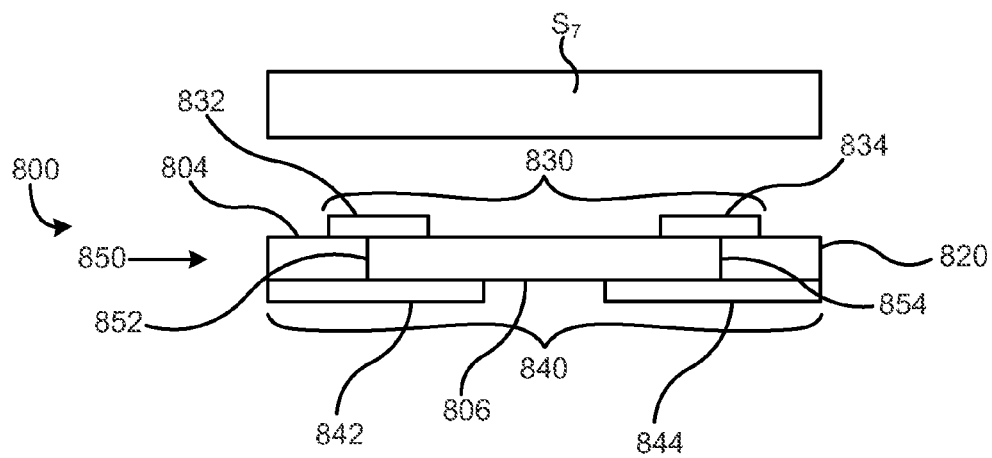


FIG. 19

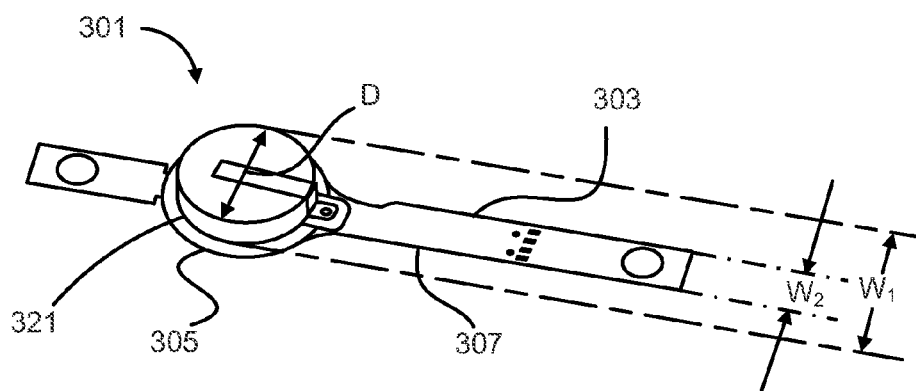


FIG. 20

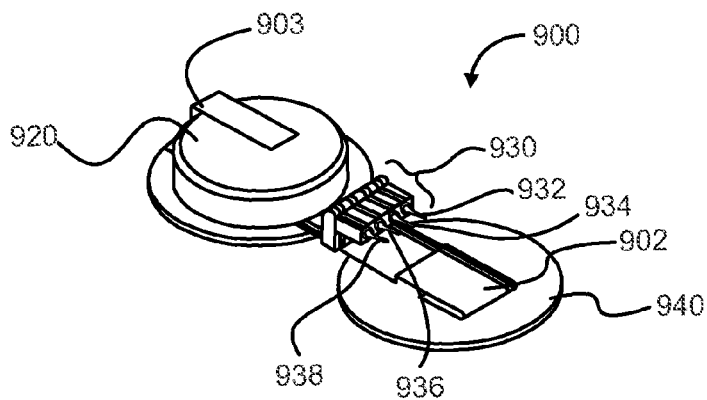


FIG. 21

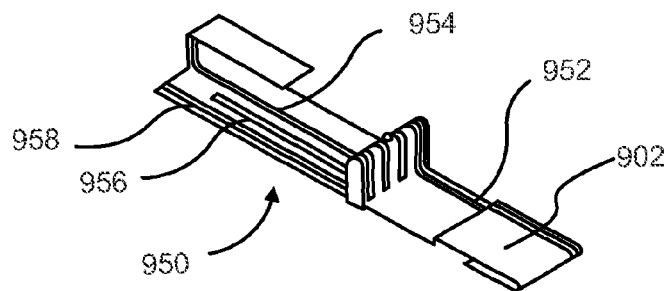


FIG. 22

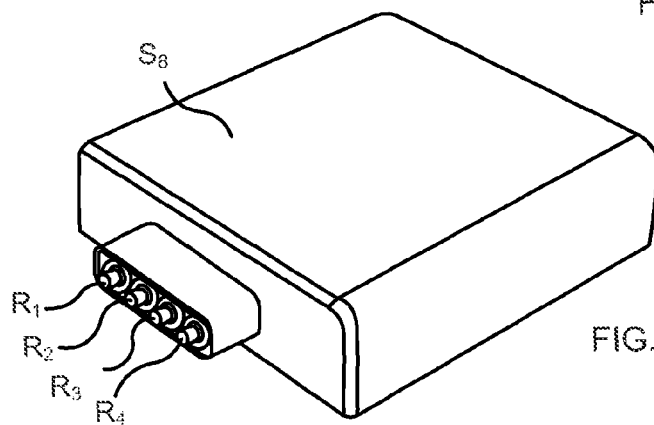


FIG. 23

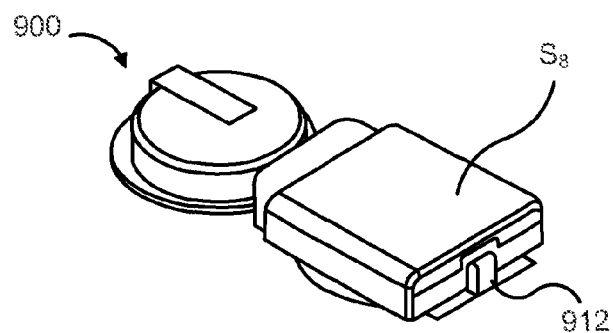


FIG. 24

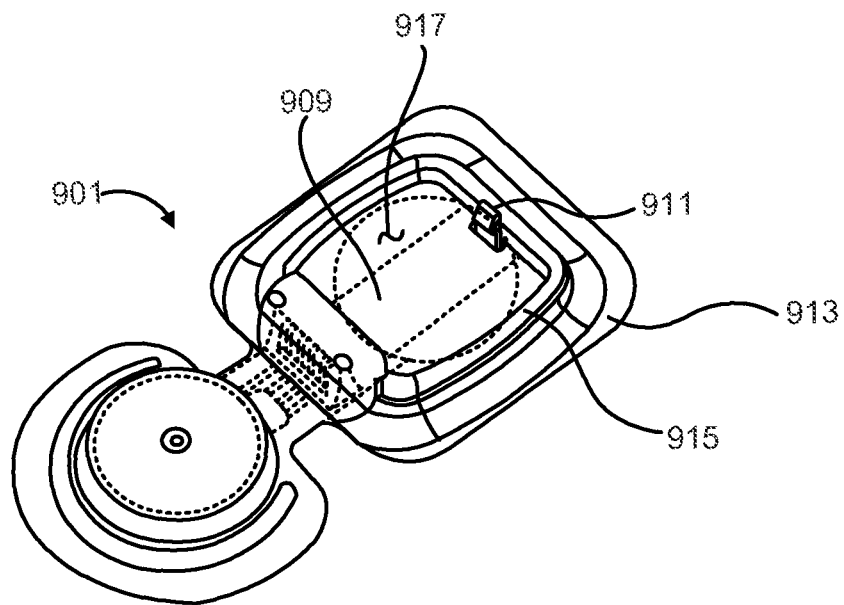


FIG. 25

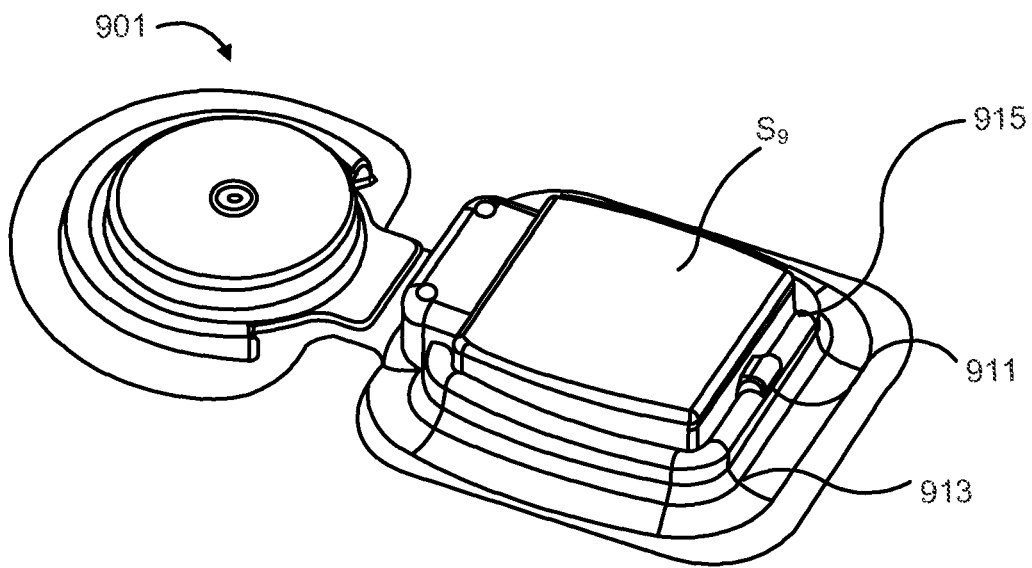


FIG. 26

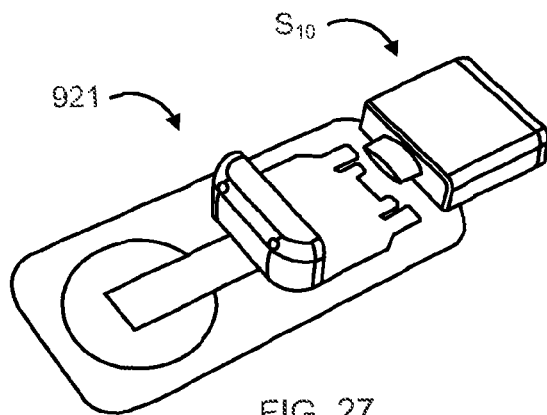


FIG. 27

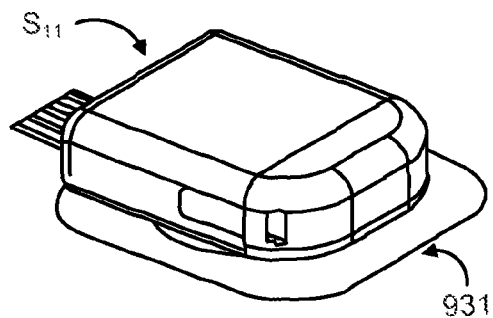


FIG. 28

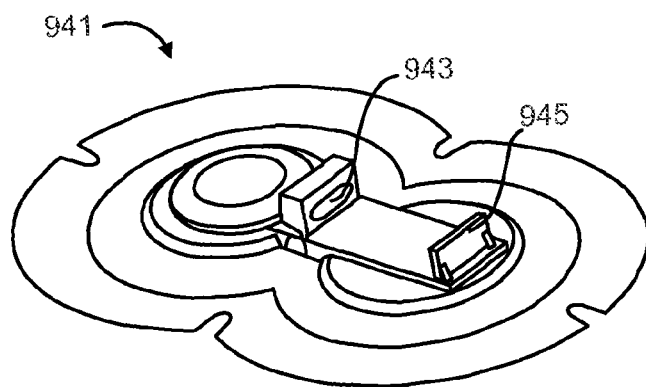


FIG. 29

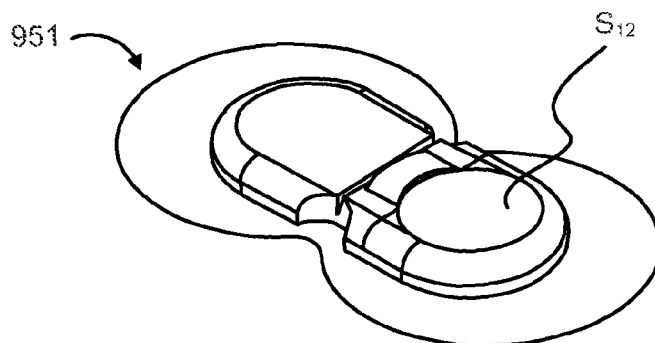
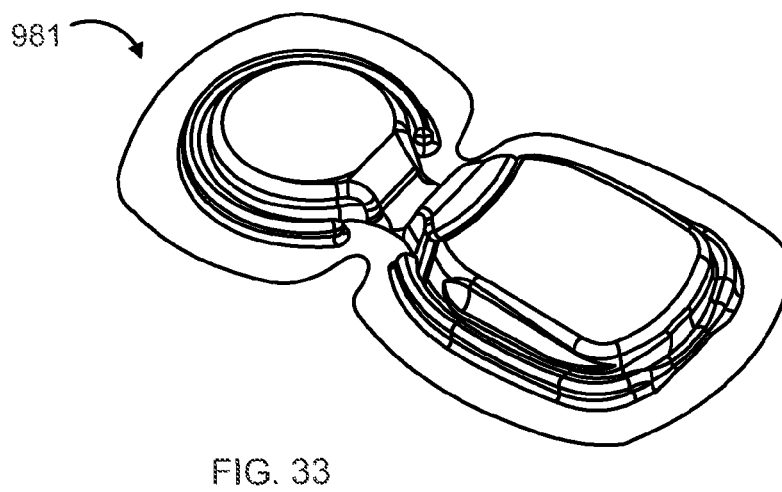
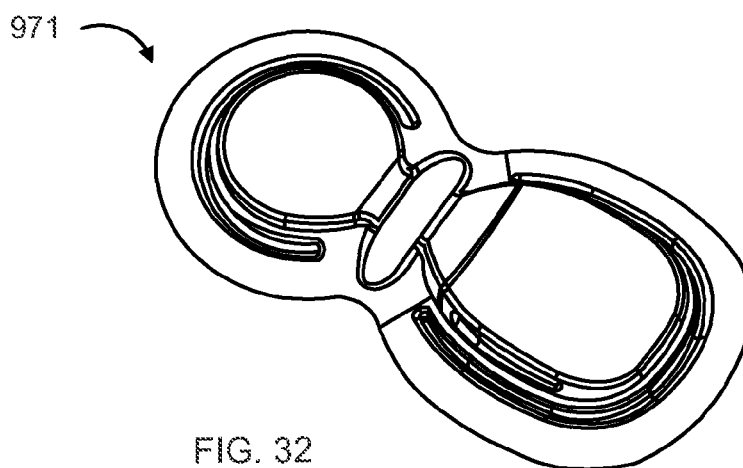
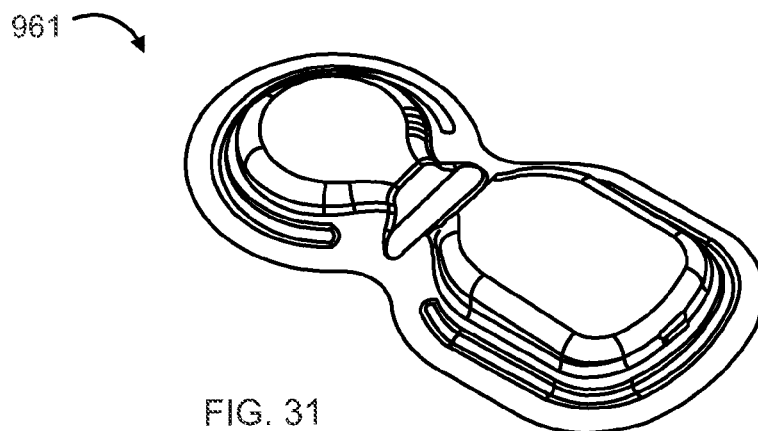


FIG. 30





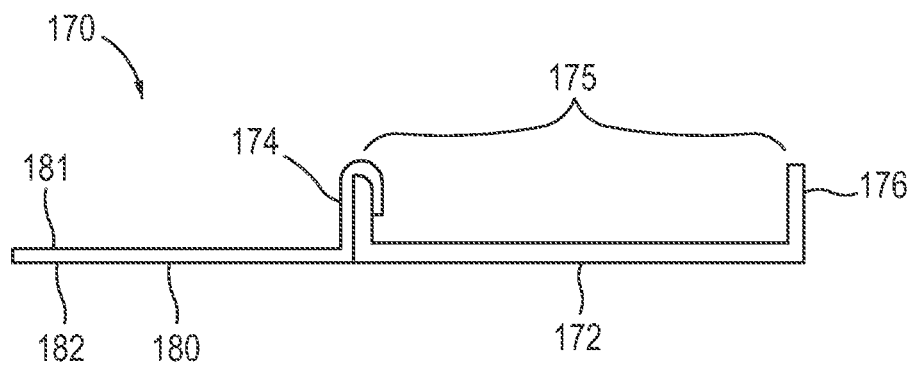


FIG. 34

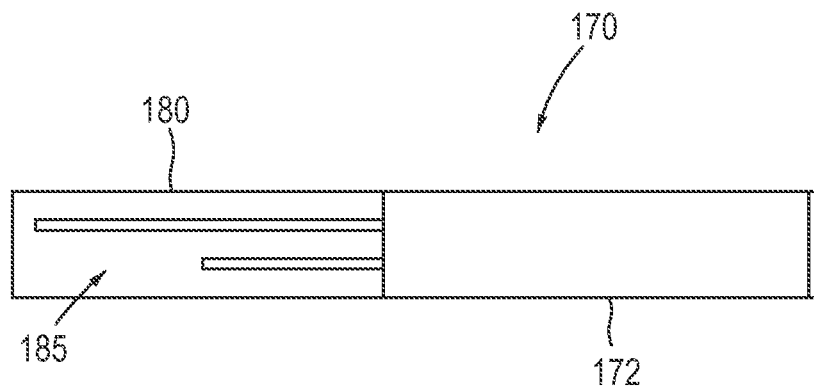


FIG. 35

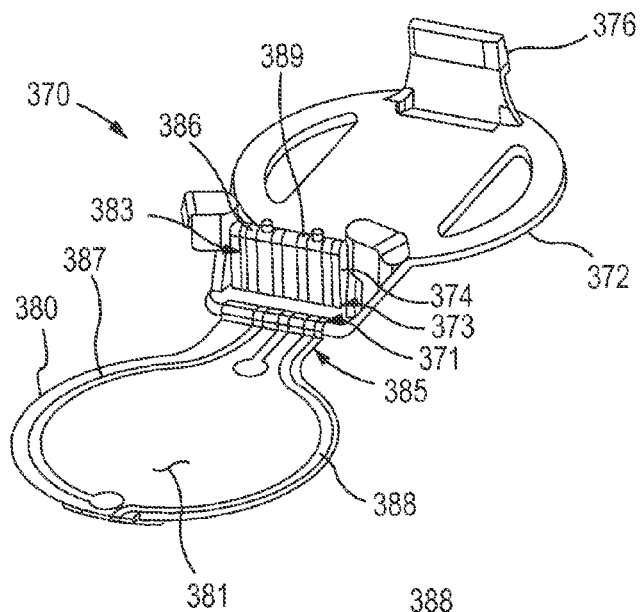


FIG. 36

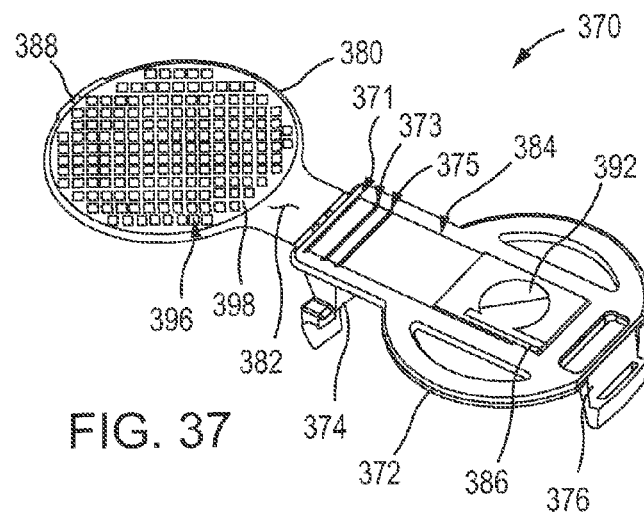


FIG. 37

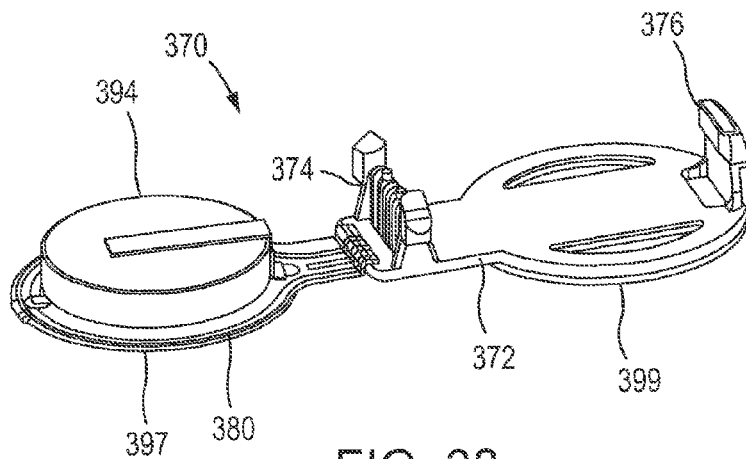


FIG. 38

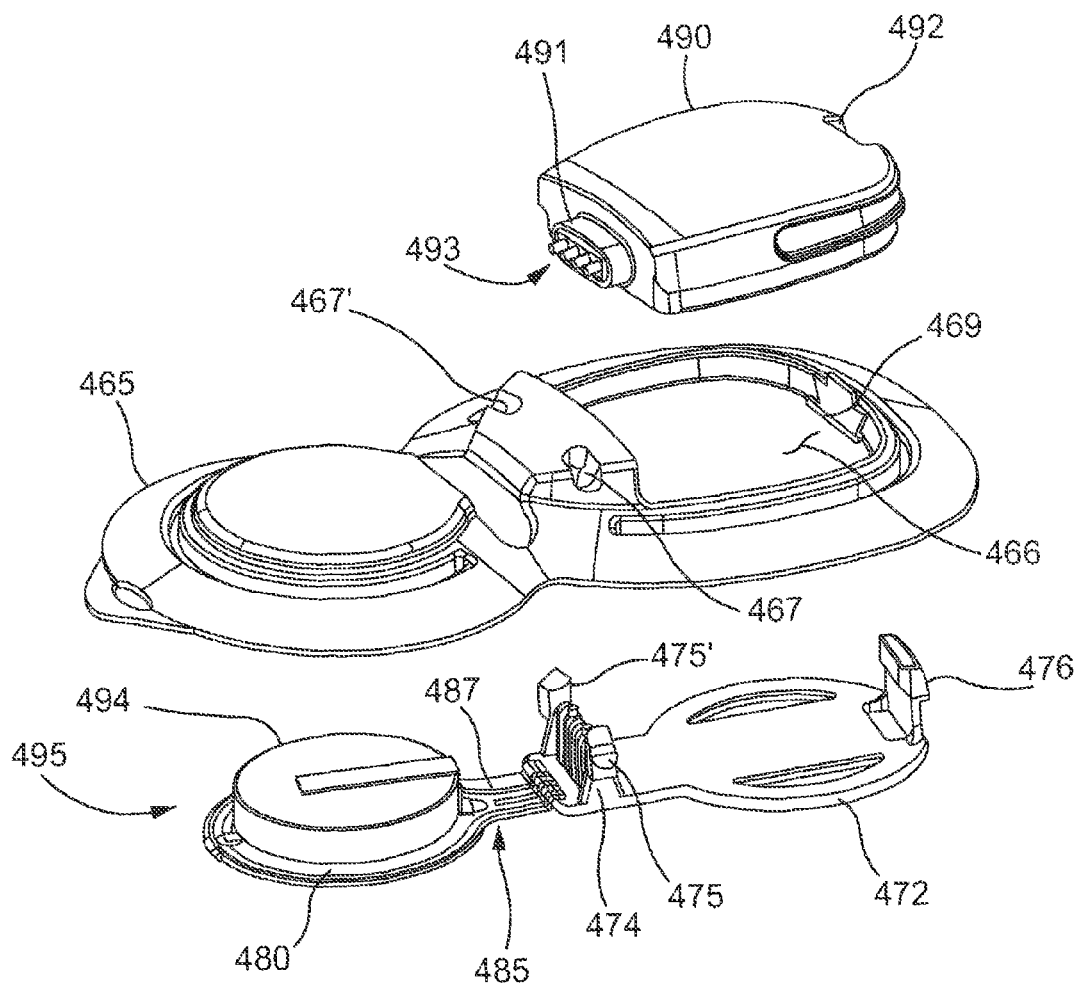


FIG. 39

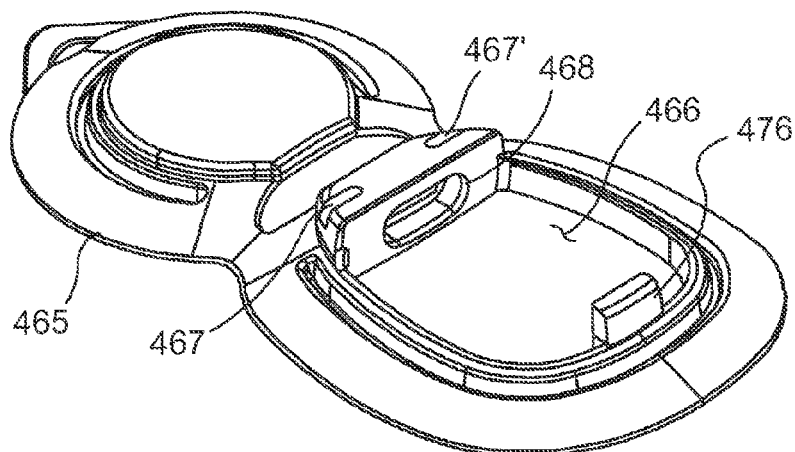


FIG. 40

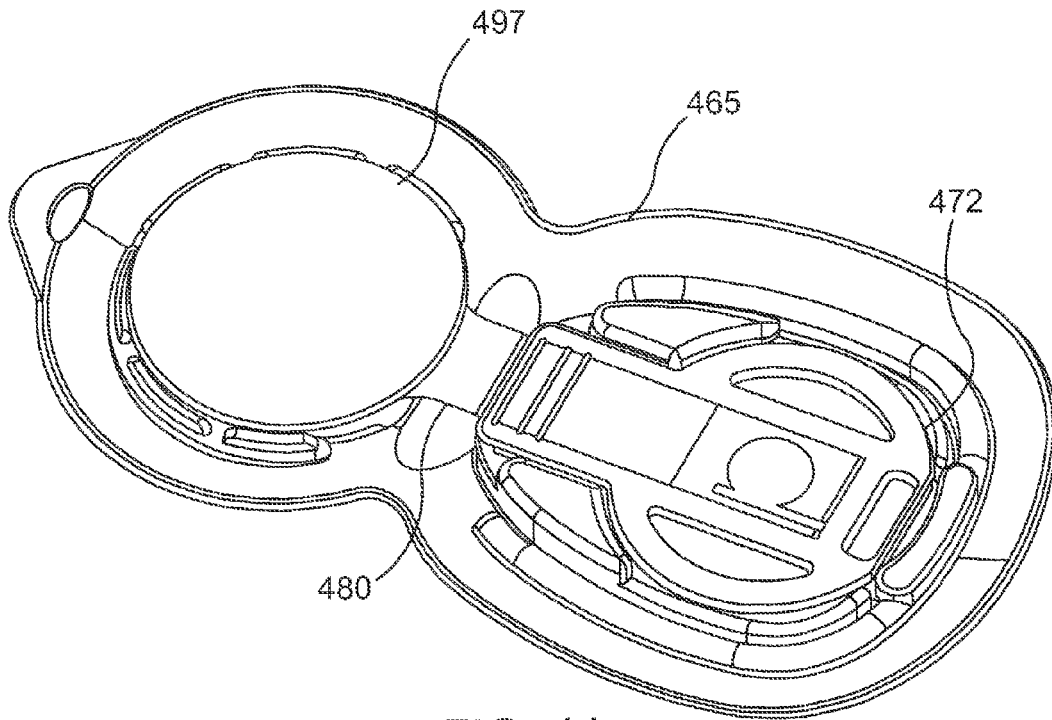


FIG. 41

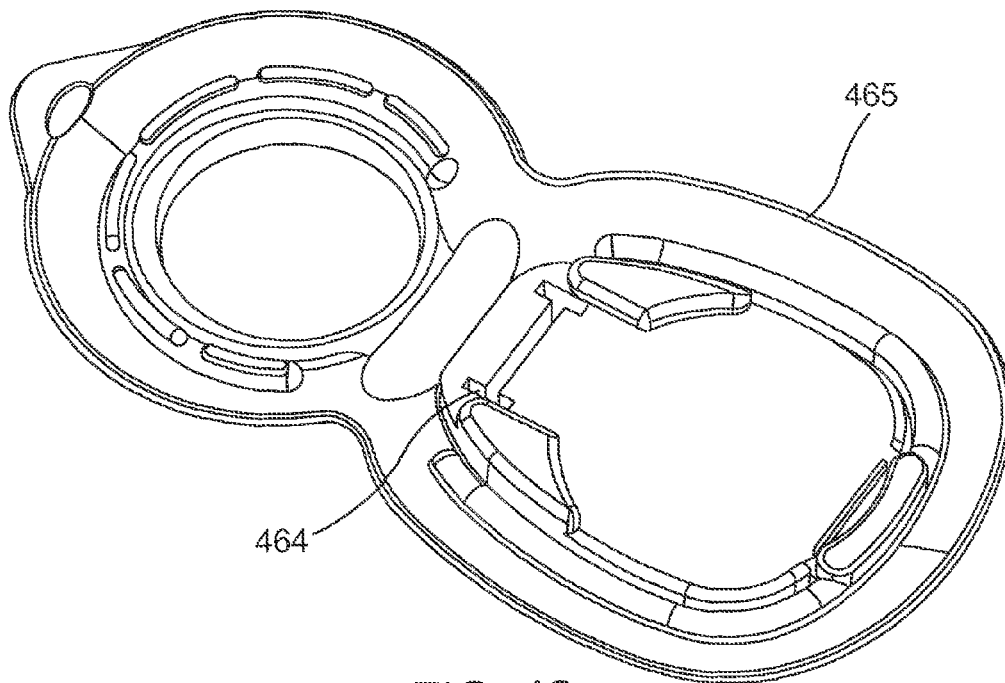


FIG. 42

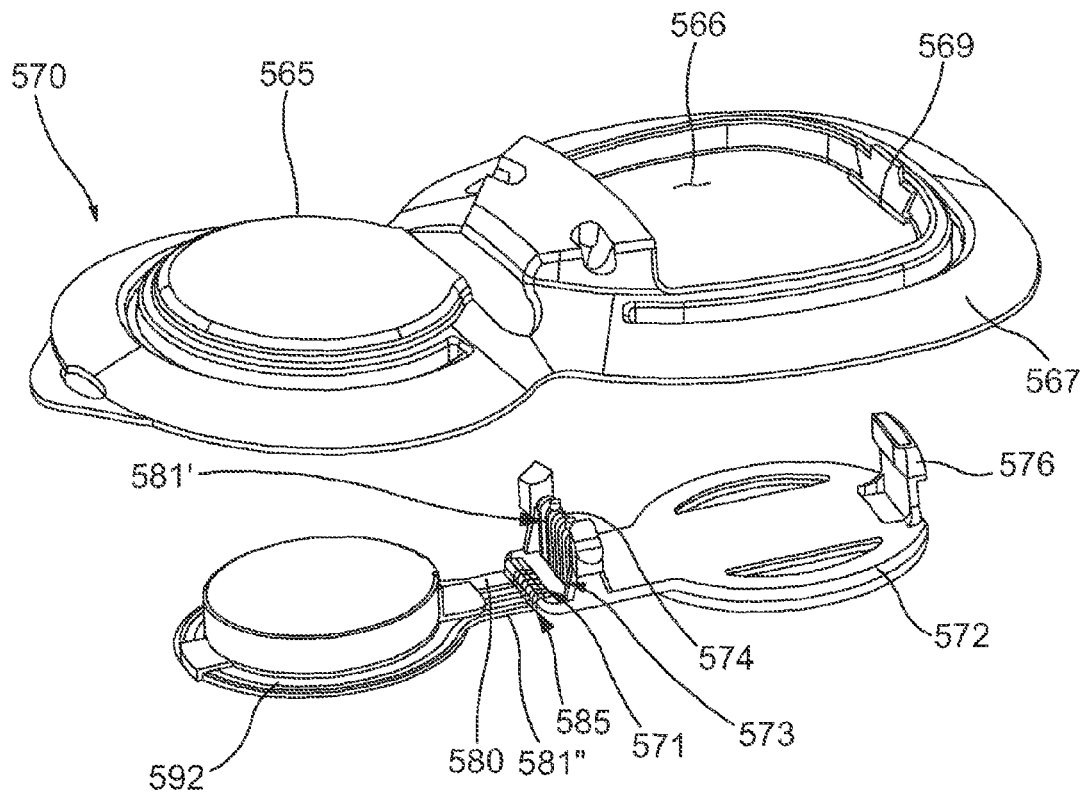


FIG. 43

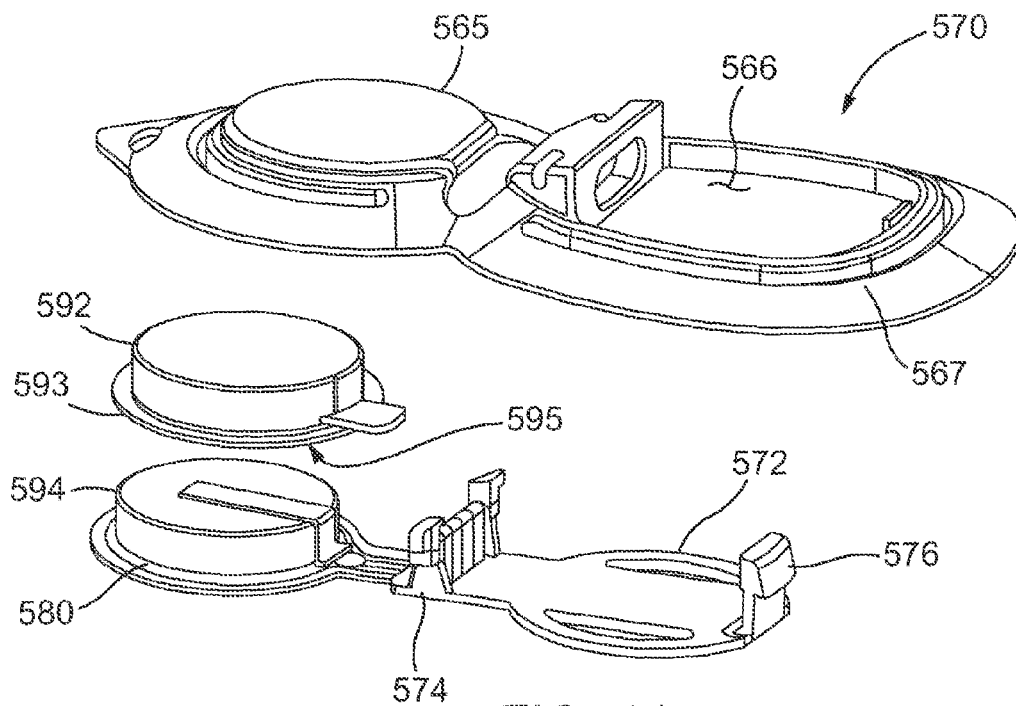


FIG. 44

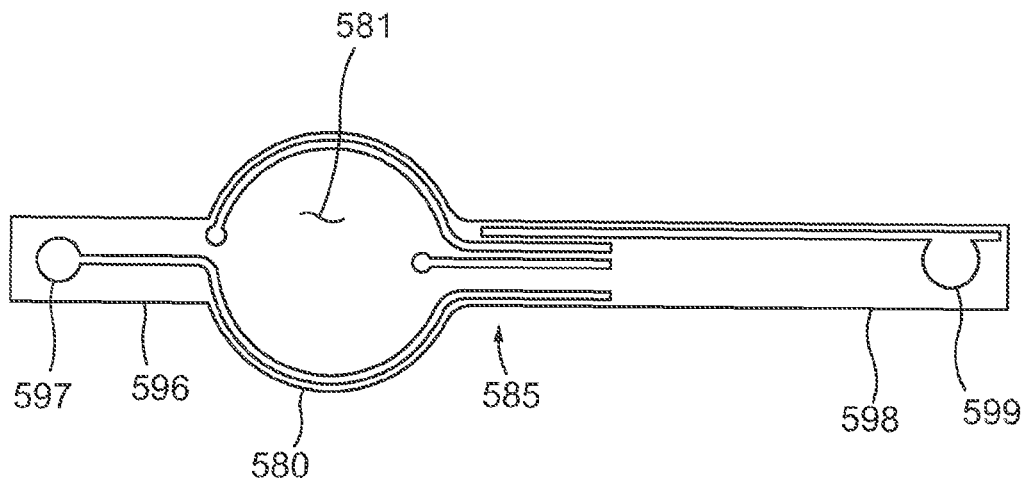


FIG. 45

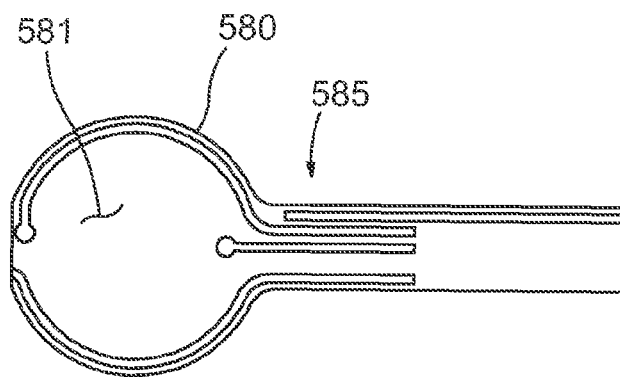


FIG. 46

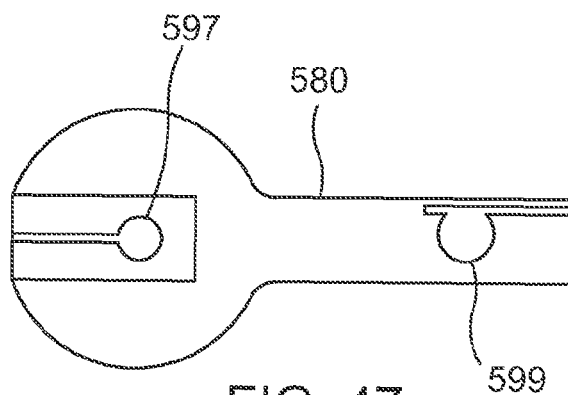


FIG. 47

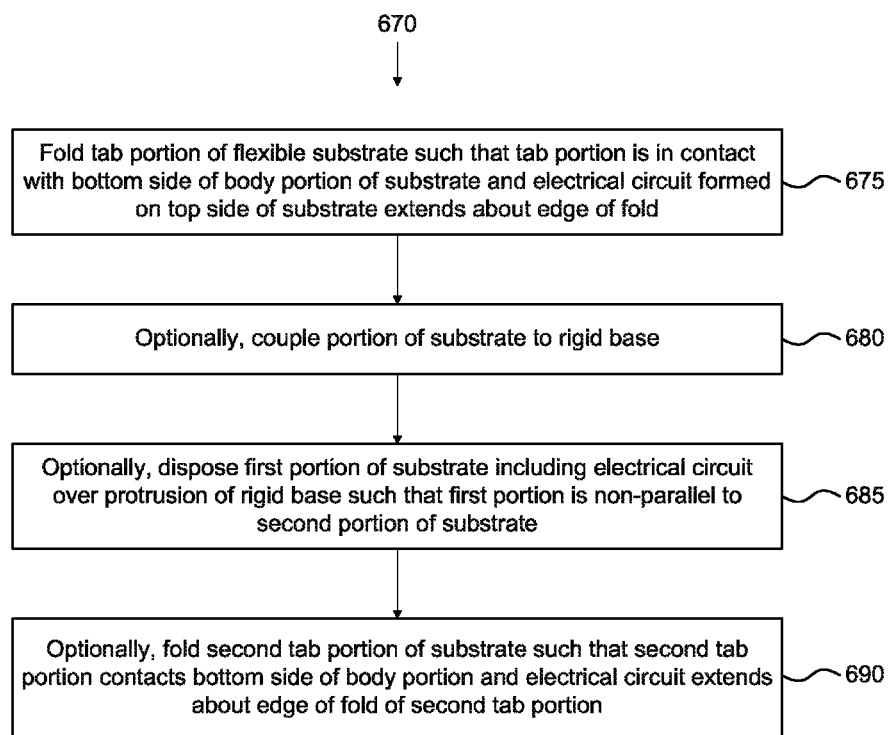


FIG. 48



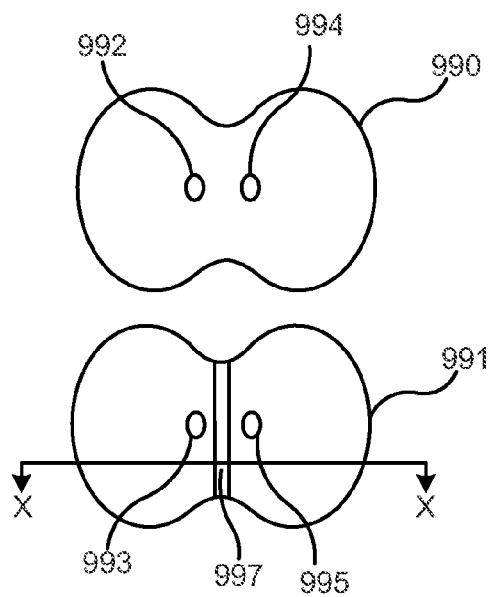


FIG. 49

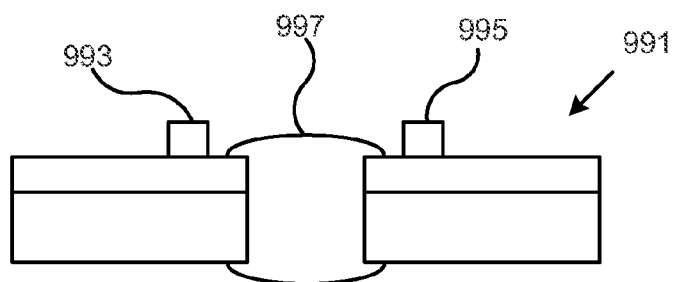


FIG. 50

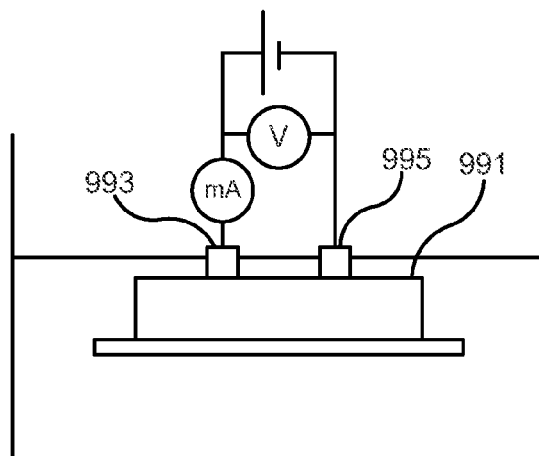


FIG. 51

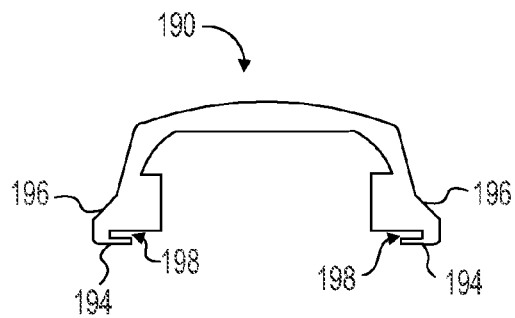


FIG. 52

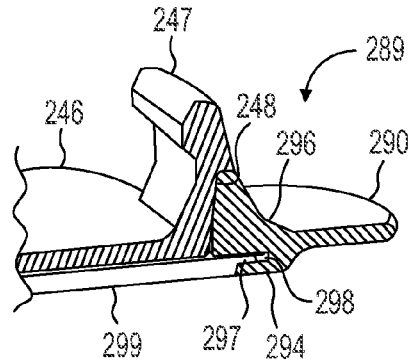


FIG. 53

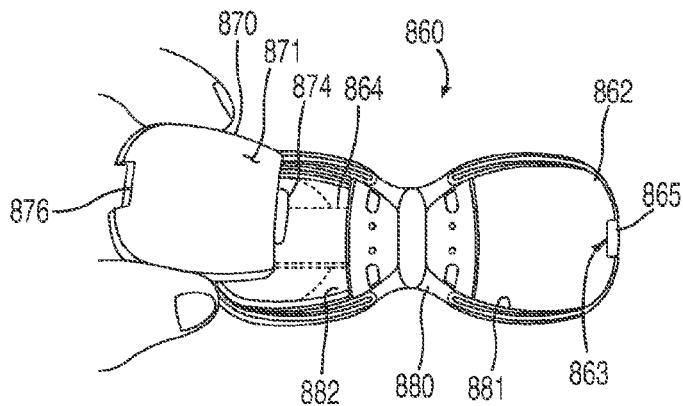


FIG. 54

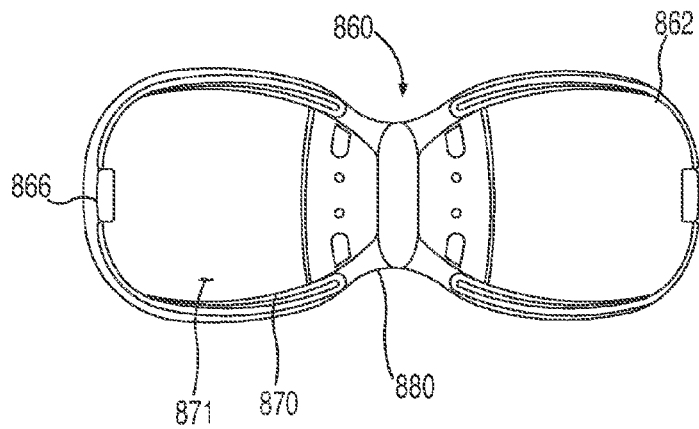


FIG. 55

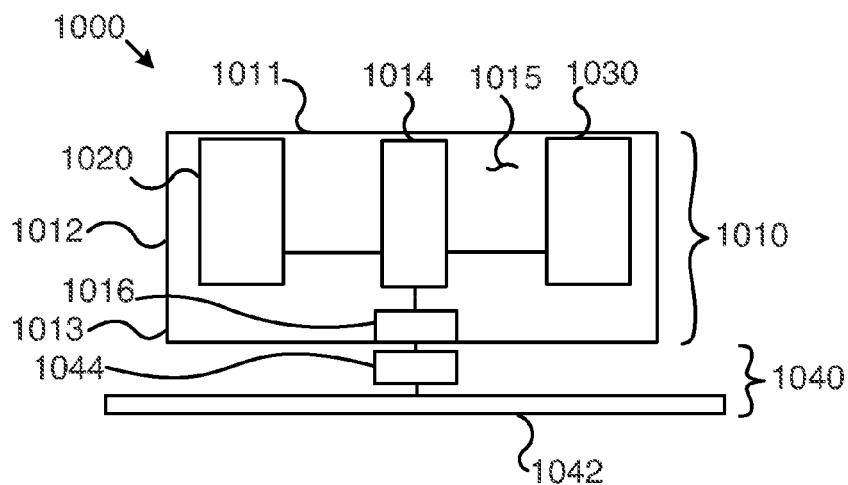


FIG. 56

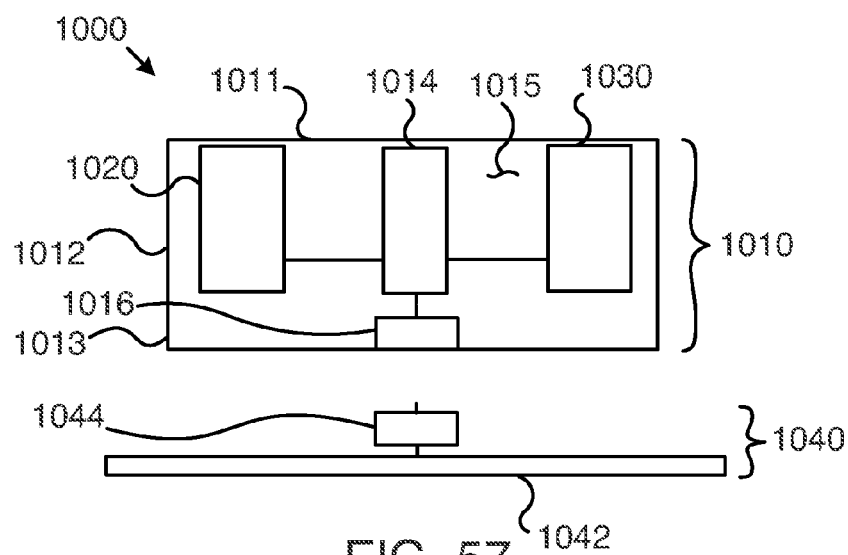


FIG. 57

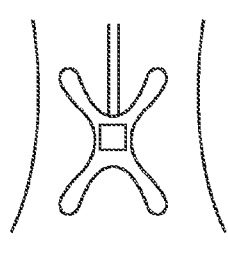


FIG. 58A

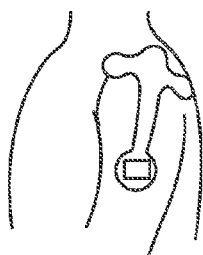


FIG. 58B

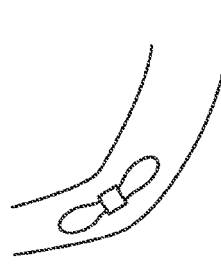
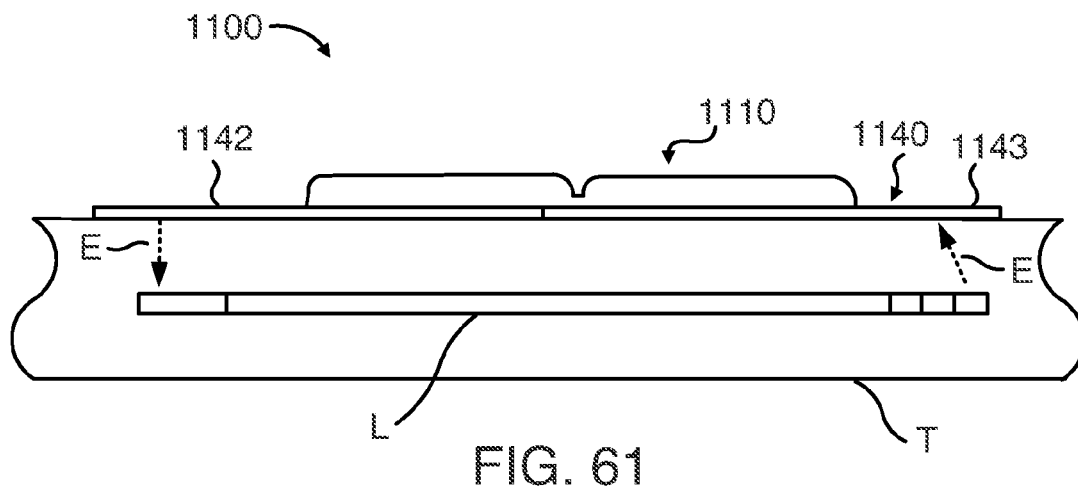
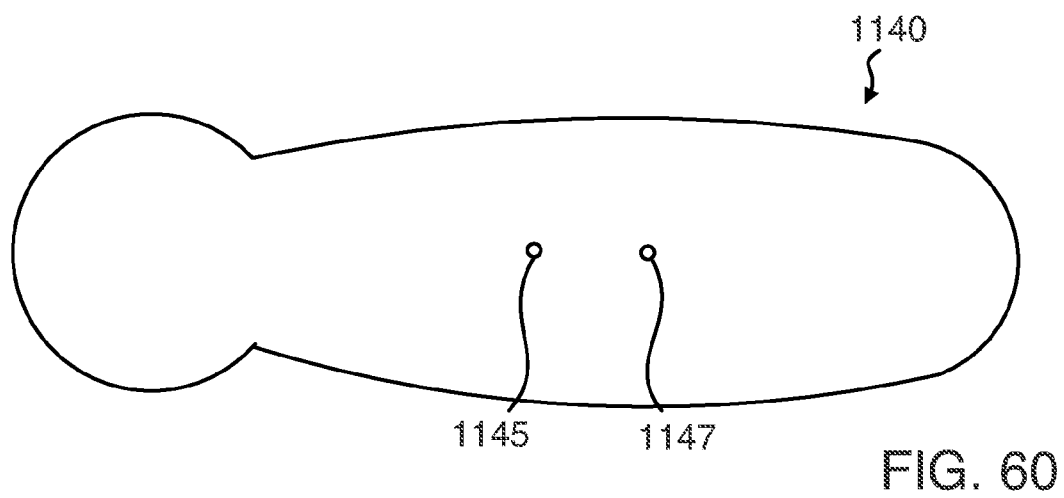
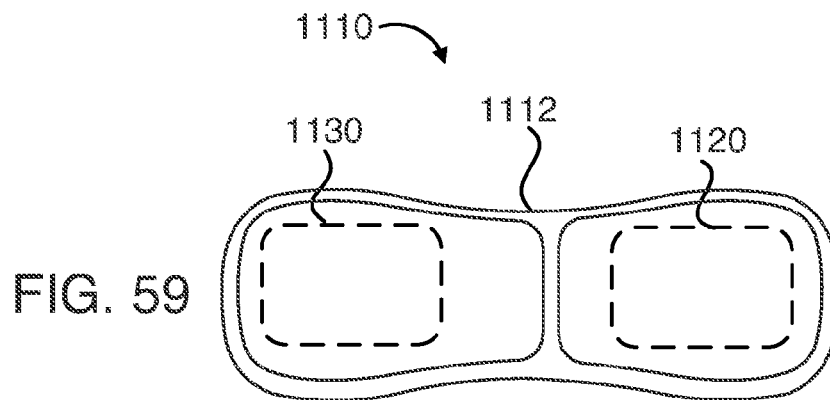


FIG. 58C



FIG. 58D



1

# SYSTEM FOR TRANSMITTING ELECTRICAL CURRENT TO A BODILY TISSUE

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a U.S. National Stage Entry of and claims priority under 35 U.S.C. §§120 and 371 to International Patent Application No. PCT/US2010/058525 filed Dec. 1, 2010, which is a continuation-in-part of U.S. patent application Ser. No. 12/628,273 filed Dec. 1, 2009, now U.S. Pat. No. 8,738,137, which is a continuation-in-part of U.S. patent application Ser. No. 12/197,849 filed Aug. 25, 2008, now U.S. Pat. No. 8,467,880, which claims priority to U.S. Provisional Application Ser. No. 60/957,592 filed Aug. 23, 2007, each of which is entitled "System for Transmitting Electrical Current to a Bodily Tissue," and each of which is incorporated herein by reference in its entirety.

## BACKGROUND

The invention relates generally to medical devices, and specifically to a device for transmitting an electrical stimulation to a bodily tissue of a patient.

Known electrical stimulation systems are used in various medical procedures. For example, some known electrical stimulation systems are used to stimulate a response from a bodily organ or tissue of a patient, such as, for example, the heart, a muscle group or the like. Some known electrical stimulation systems are used to treat acute and/or chronic pain. One known electrical stimulation system, for example, is a transcutaneous electrical nerve stimulation (TENS) unit that provides an electrical stimulation to an electrode attached to the skin of the patient. The TENS unit includes a battery that must be sufficiently large to provide enough energy for a desired treatment period, often a period of several months, of electrical stimulation before replacement. Such a battery, however, may be obtrusive and/or burdensome for a patient to wear, for example, when the patient is in a long-term treatment program. The TENS unit is connected to the skin electrodes by wires extending from the unit to the electrodes. Exposure of such wires to moisture or fluid, for example as occurs during bathing, swimming, and/or perspiration, may result in unintended current loss or transfer, or shorting of the battery. The presence of such wires can also be cumbersome and/or aesthetically unappealing for the patient. Furthermore, the electrode can lose its electrical and/or mechanical properties within several days, so regular replacement of the electrode is required.

Some known systems are configured for use with a shorter-life battery; however, the system must be designed with a housing that can be opened to remove a used battery and to insert a new battery. Such a design can result in a bulky device that must be worn by the patient.

Some known systems necessitate several connections between an electrode patch and a stimulator. For example, known systems can include three or four connections between the patch and the stimulator. Each additional connection increases the risk that the battery and/or the electrical circuit can be shorted, for example due to the connectors being exposed to moisture, as described above.

What is needed is a compact medical device having a smaller battery configured to provide power for a greater duration or a duration similar to the length of time during which an electrode retains its electrical and/or mechanical properties on a body of a patient. A need also exists for a

2

compact medical device having a rechargeable battery configured to be rechargeable over a greater period of time and that is removably coupleable to a disposable electrode base. A need also exists for a compact medical device that is configured to reduce the risk of a short circuit and/or leakage of an electrical current, such as by having a reduced number of mechanical connections with an external stimulator and/or by having water-resistant components. A need exists for a medical device capable of conforming to the curvature of a bodily tissue and providing structural integrity to support an electronic device. A need also exists for a medical device having a simplified manufacturing and/or assembly process.

## SUMMARY OF THE INVENTION

In some embodiments, an apparatus includes a substantially rigid base and a flexible substrate. The substantially rigid base has a first protrusion and a second protrusion, and is configured to be coupled to an electronic device. The flexible substrate has a first surface and a second surface, and includes an electrical circuit configured to electronically couple the electronic device to at least one of an electrode a battery, or an antenna. The flexible substrate is coupled to the base such that a first portion of the second surface is in contact with the first protrusion. A second portion of the second surface is non-parallel to the first portion.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of an apparatus according to an embodiment.

FIG. 2 is a top view of an apparatus according to an embodiment.

FIGS. 3A-3B are perspective views of a negative terminal and a positive terminal, respectively, of a portion of the apparatus of FIG. 2.

FIG. 4 is a bottom view of the apparatus of FIG. 2.

FIG. 5 is a top view of the apparatus of FIG. 2 with a portion of the apparatus in a covering.

FIG. 6 is a top view of the apparatus of FIG. 5 coupled to an external stimulator.

FIGS. 7-8 are side views of the apparatus of FIG. 2 coupled to an external stimulator and disposed on bodily tissue and delivering an electrical current to the bodily tissue and to an implanted conductive lead, respectively.

FIGS. 9A-9C are side views of portions of apparatus according to embodiments.

FIGS. 10-14 are side views of an apparatus according to embodiments and an external stimulator.

FIGS. 15-18 are top views of an antenna of an apparatus according to embodiments.

FIG. 19 is a side view of an apparatus according to an embodiment and an external stimulator.

FIG. 20 is a perspective view of an apparatus according to an embodiment.

FIG. 21 is a perspective view of a portion of an apparatus according to an embodiment.

FIG. 22 is a perspective view of a portion of the apparatus of FIG. 21.

FIG. 23 is a perspective view of an external stimulator configured for use with the apparatus of FIG. 21.

FIG. 24 is a perspective view of the apparatus of FIG. 21 and the external stimulator of FIG. 23.

FIG. 25 is a perspective and partially transparent view of an apparatus according to an embodiment.

FIG. 26 is a perspective view of the apparatus of FIG. 25 and an external stimulator.

FIG. 27 is a perspective view of an apparatus according to an embodiment and an external stimulator.

FIG. 28 is a perspective view of a portion of an apparatus according to an embodiment and an external stimulator.

FIG. 29 is a perspective view of an apparatus according to an embodiment.

FIG. 30 is a perspective view of an apparatus according to an embodiment and an external stimulator.

FIGS. 31-33 are perspective views of apparatus according to embodiments and an external stimulator.

FIG. 34 is a side view of an apparatus according to an embodiment.

FIG. 35 is a top view of the apparatus of FIG. 34.

FIGS. 36 and 37 are top and bottom perspective views, respectively, of a portion of a stimulator assembly according to an embodiment.

FIG. 38 is a perspective view of the stimulator assembly of FIG. 36 including a battery.

FIG. 39 is an exploded perspective view of a stimulator assembly according to an embodiment.

FIG. 40 is a perspective view of a portion of the stimulator assembly shown in FIG. 42.

FIG. 41 is a bottom view of the stimulator assembly of FIG. 39.

FIG. 42 is a top view of the stimulator assembly of FIG. 39 with a portion of the housing removed.

FIG. 43 is an exploded perspective view of a stimulator assembly according to an embodiment.

FIG. 44 is an exploded perspective view of the stimulator assembly of FIG. 43.

FIG. 45 is a top view of a portion of the stimulator assembly of FIG. 43 in a first configuration.

FIGS. 46-47 are top and bottom views, respectively, of a portion of the stimulator assembly of FIG. 43 in a second configuration.

FIG. 48 is a flow chart of a method of assembling a portion of a stimulator system according to an embodiment.

FIG. 49 is a top view of two experimental apparatus according to embodiments.

FIG. 50 is a cross-sectional view of an apparatus of FIG. 49 taken along line X-X.

FIG. 51 is a front view of an apparatus of FIG. 49 partially immersed in a liquid.

FIG. 52 is a front, cross-sectional view of a portion of a housing according to an embodiment.

FIG. 53 is a perspective, cross-sectional view of a portion of a stimulator assembly according to an embodiment.

FIGS. 54-55 are top views of a stimulator assembly according to an embodiment in a first configuration and a second configuration, respectively.

FIGS. 56-57 are schematic illustrations of a stimulator system according to an embodiment in a first coupled configuration and a second uncoupled configuration, respectively.

FIGS. 58A-58D are front views of stimulator systems according to embodiments disposed on bodily tissue.

FIGS. 59-60 are top views of a stimulator assembly and an electrode assembly, respectively, of a stimulator system according to an embodiment.

FIG. 61 is a side view of the stimulator system of FIGS. 59-60 disposed on bodily tissue and delivering an electrical current to an implanted conductive lead.

#### DETAILED DESCRIPTION

Apparatus and methods for transmitting an electrical signal (e.g., a current or stimulation) from an electronic device (e.g.,

an external stimulator) to a bodily tissue of a patient are described herein. Also described herein are methods for assembling a portion of a stimulator assembly for use in transmitting the electrical signal from the electronic device to the bodily tissue. In some embodiments, an apparatus is configured to be disposed on bodily tissue (e.g., skin) of a patient. The apparatus is configured to receive an electrical input from an external stimulator via a connector and to transmit the electrical input as an electrical current to an electrode disposed on or proximate to the bodily tissue. In this manner, the apparatus transmits the electrical stimulation to the bodily tissue.

As used herein, bodily tissue can include any tissue of a patient suitable for receiving and/or conveying an electrical stimulation. Bodily tissue can include, for example, nervous tissue, such as a nerve, the spinal cord, or another component of the peripheral or central nervous system. In another example, bodily tissue can include muscle tissue, such as, for example, skeletal muscle, smooth muscle, or cardiac muscle. Specifically, bodily tissue can include a group of tissues forming an organ, such as, for example, the skin, lungs, cochlea, heart, bladder, or kidney. In still another example, bodily tissue can include connective tissue, such as, for example, skin, bone or bone-like tissue.

The apparatus is configured to treat a variety of medical conditions, including acute and/or chronic pain, and/or to activate a motor point. For example, the apparatus can be configured to transmit an electrical current that at least partially activates conduction and/or propagation of action potentials (nerve impulses) along the axons of a target nerve associated with a target bodily tissue. In another example, the apparatus can be configured to transmit to the bodily tissue an electrical current that at least partially blocks the conduction and/or propagation of action potentials along the axons of the target nerve associated with the target bodily tissue.

The apparatus can be configured for transcutaneous and/or percutaneous stimulation of the target bodily tissue. In a treatment or procedure for transcutaneous stimulation, for example, the apparatus is configured to transmit an electrical stimulation through bodily tissue from a first electrode positioned on a first location of the patient's skin to a second electrode positioned on a second location on the patient's skin different from the first location. The pathway of the electrical current through the bodily tissue of the patient is a transcutaneous stimulation pathway. In a treatment or procedure for percutaneous stimulation, for example, the apparatus is configured to transmit an electrical stimulation to bodily tissue via an electrical lead. The electrical lead helps direct the electrical current to the target bodily tissue. In some procedures, the electrical lead can be completely implanted within the bodily tissue. In other procedures, the electrical lead is partially implanted within the bodily tissue such that a portion of the lead extends through the skin.

In some embodiments, the apparatus can be a portion of a system for stimulation of the target bodily tissue. For example, in some embodiments, the apparatus includes a substrate and a base, wherein the apparatus is configured for use with an electronic device to deliver an electrical current to the target bodily tissue. In another example, the apparatus includes a housing configured to be disposed about a portion of a stimulator assembly that is configured to transmit an electrical current to the target bodily tissue.

As used in this specification, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, the term "a material" is intended to mean one or more materials, or a combination thereof.

5

FIG. 1 is a schematic illustration of an apparatus 100 according to an embodiment. The apparatus 100 is configured to transmit an electrical current from a stimulator (not shown) through a bodily tissue of a patient. In this manner, the apparatus 100 is configured to stimulate a target bodily tissue. The apparatus 100 can be, for example, an electrode-battery assembly.

The apparatus 100 is configured to be disposed on or proximate to a patient's body, for example, on the skin of the patient. The apparatus 100 can be coupled to the skin of the patient with an adhesive, a bandage, or the like, or any combination of the foregoing.

The apparatus 100 includes a substrate 102, a power source 120, a connector 132, electrical circuitry 150, and an electrode assembly 140. The substrate 102 has a first surface 104 and a second surface 106 different than the first surface 104. The substrate 102 is configured to be disposed on or proximate to the body of the patient. When the apparatus 100 is disposed on the patient's body, the second surface 106 of the apparatus faces the patient's tissue, e.g., the skin.

The power source 120 is configured to provide power to an external stimulator (not shown) coupled to the apparatus 100. The power source 120 can be any suitable energy supplying source. For example, in some embodiments, the power source 120 is a battery. In some embodiments, the power source 120 is an ultracapacitor or a supercapacitor. The power source 120 is coupled to the substrate 102. In the schematic illustration, the power source 120 has a positive terminal 122 and a negative terminal 124. Each of the positive terminal 122 and the negative terminal 124 are coupled to the substrate 102.

The connector 132 is configured to electrically couple the external stimulator to the power source 120 and/or the electrical circuitry 150. The connector 132 can be any suitable mechanism for electrically coupling the external stimulator and the power source 120. For example, in some embodiments, the connector 132 is configured to provide both a mechanical and an electrical connection between the apparatus 100 and the external stimulator. Said another way, when the external stimulator is mechanically coupled to the apparatus 100 via the connector 132, the external stimulator is also placed in electrical communication with the power source 120. The connector 132 can be any suitable connector, including but not limited to, a snap-fit connector. In some embodiments, the connector 132 is a metal electrode. In some embodiments, the connector 132 is configured to provide a wireless electrical connection between the external stimulator and the power source 120. In some embodiments, for example, the connector is an antenna configured to transmit a signal to and/or receive a signal from the external stimulator. In some embodiments, the connector is a conductive ink, a wire, or the like.

The connector 132 is disposed proximate to the first surface 104 of the substrate 102. In some embodiments, for example, the connector is embedded in the first surface 104 of the substrate 102. In some embodiments, the connector 132 is disposed on top of the first surface 104 of the substrate 102. For example, the connector 132 can be a conductive ink printed onto the first surface 104 substrate. In still other embodiments, a portion of the connector 132 is embedded in the substrate and another portion of the connector extends from the first surface 104. As illustrated in FIG. 1, the connector 132 is electrically coupled to at least one of the positive terminal 122 and the negative terminal 124 of the power source 120.

The electrical circuitry 150 is coupled to the substrate 102. The electrical circuitry 150 is configured to electrically couple the connector 132 to the at least one of the positive

6

terminal 122 and the negative terminal 124 of the power source 120. In some embodiments, for example, the electrical circuitry 150 includes a wire configured to electrically connect the connector to the power source 120. In some embodiments, a portion of the electrical circuitry 150 is a pathway of conductive ink printed onto the substrate 102.

At least one of the connector 132 or the electrical circuitry 150 is configured to prevent a short circuit of the electrical circuit contained therein. The electrical circuitry 150 can include a variety of suitable mechanisms configured to prevent shorting the electrical circuit (including shorting of the power source 120). For example, in some embodiments, the electrical circuitry 150 includes a fuse configured to open the electrical circuit in the presence of a threshold electrical load. In some embodiments, the electrical circuitry 150 includes a switch biased towards an open position such that the electrical circuit is incomplete until the switch is moved to a closed position. In some embodiments, the electrical circuitry 150 includes a diode configured to prevent flow of an electrical current in an undesired direction. In some embodiments, the connector 132 is configured as a wireless connector. For example, the connector 132 can be an antenna or a coil configured to wirelessly transmit and/or receive an electrical current between the external stimulator and the power source 120. In this manner, the connector 132 can be disposed below a surface of the apparatus 100 or otherwise covered such that the connector 132 is isolated from sources of moisture.

The electrode assembly 140 is coupled to the second surface 106 of the substrate 102. The electrode assembly 140 includes at least one electrode 142. The electrode 142 is configured to contact bodily tissue. For example, in some embodiments, the apparatus 100 includes a gel electrode 142 configured to adhere to the patient's skin. The electrode 142 is configured to facilitate transmission of an electrical current through the bodily tissue.

FIGS. 2-8 illustrate an apparatus 200 according to an embodiment. The apparatus 200 is configured to be disposed on a tissue (e.g., the skin) of a patient. The apparatus 200 includes a substrate 202, a power source 220, a connection assembly 230, electrical circuitry 250, and an electrode assembly 240.

The substrate 202 of the apparatus 200 is a printed circuit board ("PCB"). The PCB 202 has a first surface 204 (see, e.g., FIG. 2) and a second surface 206 (see, e.g., FIG. 4). In use, the second surface 206 of the PCB 202 faces the body of the patient and the first surface 204 faces away from the body of the patient. The PCB 202 is flexible such that the PCB can substantially conform to the contours of the portion of the patient's body on which the apparatus 200 is disposed. For example, the PCB 202 can be configured to be flexible such that the PCB conforms to the curvature of a patient's arm, leg, or back. In this manner, the PCB 202 is configured to facilitate positioning and placement of the apparatus 200 on the patient's body.

The power source 220 is configured to provide power to an external stimulator S (see, e.g., FIG. 6) coupled to the apparatus 200. The power source 220 is a battery coupled to the PCB 202. Specifically, the battery 220 is coupled to the PCB 202 by electrically conductive tabs 226, 228. As illustrated in FIGS. 2, 3A, and 3B, the battery has a positive terminal 222 and a negative terminal 224. A first electrically conductive tab 226 is coupled to the positive terminal 222. A second electrically conductive tab 228 is coupled to the negative terminal 224. Each of the first and second electrically conductive tabs 226, 228 are coupled to the PCB 202. The electrically conductive tabs 226, 228 can be coupled to the PCB by any suitable coupling mechanism. For example, each electrically

conductive tab **226**, **228** can be coupled to the PCB **202** by at least one of a solder joint, a braze joint, a weld, an adhesive, a mechanical coupler, or the like, or any combination of the foregoing. Each of the first and second electrically conductive tabs **226**, **228** provides an electrical connection between its respective positive terminal **222** or negative terminal **224** of the battery **220** and the electrical circuitry **250**, as described in more detail herein.

The connection assembly **230** includes a first connector **232**, a second connector **234**, and a third connector **236**. The connectors **232**, **234**, **236** are disposed proximate to the first surface **204** of the PCB **202**. The first and second connectors **232**, **234**, in conjunction with the electrical circuitry **250**, are configured to electrically couple the battery **220** and the external stimulator S. Specifically, the first connector **232** is electrically coupled to the positive terminal **222** of the battery **220** via the electrical circuitry **250**, and the second connector **234** is electrically coupled to the negative terminal **224** of the battery via the electrical circuitry.

The electrical circuitry **250** is at least partially coupled to the PCB **202**. In some embodiments, at least a portion of the electrical circuitry **250** is a conductive material printed onto the PCB **202**. As illustrated in FIG. 2, the electrical circuitry **250** includes a first electrical pathway **252**, a second electrical pathway **254**, and a third electrical pathway **256**. The first electrical pathway **252** extends from the first connector **232** to the first electrically conductive tab **226**, which is coupled to the positive terminal **222** of the battery **220**. The first electrical pathway **252** is electrically coupled to the first electrically conductive tab **226**, such as by at least one of a solder, a weld, a braze joint, a conductive adhesive, a mechanical coupler, or the like, or any combination of the foregoing. Thus, the electrical circuitry **250**, via the first electrical pathway **252**, electrically couples the first connector **232** to the positive terminal **222** of the battery **220**.

The second electrical pathway **254** extends from the second connector **234** to the second electrically conductive tab **228**, which is coupled to the negative terminal **224** of the battery **220**. The second electrical pathway **254** is electrically coupled to the second electrically conductive tab, such as by at least one of a solder, weld, braze joint, a conductive adhesive, a mechanical coupler, or the like, or any combination of the foregoing. Thus, the electrical circuitry **250**, via the second electrical pathway **254**, electrically couples the second connector **234** to the negative terminal **224** of the battery **220**. In this manner, when the external stimulator S is coupled to the apparatus **200** via the first and second connectors **232**, **234**, a power circuit is completed between the battery **220** and the external stimulator. When the power circuit is completed, the battery **220** can provide power to the external stimulator S, which the external stimulator can use to generate an electrical current for stimulating bodily tissue, as described in more detail herein.

The connection assembly **230** is configured to prevent a short circuit of the electrical circuit. The connection assembly **230** includes a hydrophobic barrier **218** coupled to the substrate **202**. As illustrated in FIG. 2, the hydrophobic barrier is a Y-shaped barrier configured to increase impedance of the electrical current between the first connector **232**, second connector **234**, and/or the third connector **236**, for example, when a portion of the substrate is wetted. An experiment testing the impedance of such a barrier is described below with reference to FIGS. 20-22. In use, the apparatus **200** may be wetted or otherwise exposed to a source of moisture, for example water or perspiration, which can create a leakage path for the electrical current between the first connector **232**, the second connector **234**, and/or the third connector **236** of

the connection assembly **230**. Such a leakage path for the electrical current can interfere with delivery of the electrical current intended to stimulate the bodily tissue and/or can cause leakage and discharge of the battery **220**. The hydrophobic barrier **218** increases the impedance between at least one of the connectors **232**, **234**, **236** and another of the connectors **232**, **234**, **236** and/or the wet surface of the substrate **202**. The hydrophobic barrier **218** can be constructed of any suitable material, including, but not limited to, plastic, rubber, glue, or another substantially non-conductive material.

The electrical circuitry **250** is also configured to prevent a short circuit of the electrical circuit. Specifically, as illustrated in FIG. 2, the electrical circuitry **250** includes a fuse **258** in the second electrical pathway **254**. The fuse **258** is coupled to the PCB **202**. For example, the fuse **258** can be at least partially embedded in the PCB **202**.

The fuse **258** has a closed configuration and an open configuration. When the fuse **258** is in its closed configuration, the electrical circuitry **250** is configured to allow transfer of an electrical current through the circuitry between the battery **220** and the electrically coupled external stimulator S. In other words, the electrical circuit is closed or complete. When the fuse **258** is in an open configuration, a gap or interruption exists in the second electrical pathway **254**. In other words, the electrical circuit is open or incomplete. The transfer of electrical current through the electrical circuitry **250** between the battery **220** and the external stimulator S is inhibited when the circuit is open. As such, the battery **220** is substantially inhibited from providing power to the external stimulator S when the fuse is in its open configuration.

The fuse **258** is configured to be in (or is moved to) its open configuration in the presence of a threshold electrical load. For example, the fuse **258** can be a metal wire or strip configured to melt under an abnormally high electrical load. In another example, the fuse **258** can be configured to break under a threshold electrical load. For example, during use on the body of a patient, the connectors **232**, **234**, **236** of the connection assembly **230** can be exposed when the external stimulator S is not mechanically coupled to the apparatus **200**. The exposed connectors **232**, **234**, **236** create a risk of shorting the battery **220**, for example by exposure to fluid or an electrical charge, which can cause heating and/or explosion of the battery. The fuse **258**, however, is configured to open the electrical circuit in the presence of the threshold electrical load to prevent such a short of the battery.

The electrical circuitry **250** also forms a portion of a stimulation circuit. The stimulation circuit includes the third connector **236**, a portion of the electrical circuitry **250**, such as the third electrical pathway **256**, and the electrode assembly **240**. The stimulation circuit is complete when the external stimulator is coupled to the third connector **236**. The electrical circuitry **250** of the stimulation circuit is configured to receive an electrical current from the external stimulator via the third connector **236**. The electrical circuitry **250** is configured to transmit the electrical current to at least one of a first electrode **242** and a second electrode **244**. The electrical circuitry **250** is also configured to receive at least a portion of the electrical current from at least one of the first electrode **242** and the second electrode **244**. The electrical circuitry **250** transmits the received electrical current to at least one of the external stimulator S or the battery **220**.

The electrode assembly **240** of the apparatus **200** is coupled to the second surface **206** of the PCB **202**, as illustrated in FIG. 4. The electrode assembly **240** includes the first electrode **242** and the second electrode **244**. As illustrated in FIGS. 7-8, each of the first electrode **242** and the second electrode **244** is configured to contact bodily tissue T and to



facilitate transmission of an electrical current E through the bodily tissue, for example through subcutaneous bodily tissue located below and/or between the first electrode **242** and the second electrode **244**. The first electrode **242** is configured to facilitate transmission of the electrical current E from the external stimulator S through the bodily tissue T. The first electrode **242** can facilitate transmission of the electrical current E to an electrical lead L at least partially implanted within the bodily tissue, as illustrated in FIG. 8. The second electrode **244** is configured to receive at least a portion of the electrical current E. As illustrated in FIGS. 7-8, for example, the second electrode **244** can receive electrical current E that has passed through the bodily tissue T and/or through an electrical lead L at least partially implanted within the bodily tissue. The transmission of current to an implanted lead is described, for example, in U.S. patent application Ser. No. 11/337,824, which is incorporated herein by reference in its entirety.

The electrodes **242**, **244** are configured to adhere to bodily tissue (e.g., the skin) of the patient. Each electrode **242**, **244** of the electrode assembly **240** includes a gel on the tissue-facing surface of the electrode. The gel can be any suitable known gel including, but not limited to, wet gels, karaya-gum-based hydrogels, and/or synthetic copolymer-based hydrogels. The first electrode **242** and second electrode **244** can be, for example, a cathodic gel electrode and an anodic gel electrode, respectively.

As illustrated in FIG. 5, the apparatus **200** can be at least partially enclosed by a material **212**, such as a material configured to increase the comfort of the patient utilizing the apparatus and/or protect components of the apparatus from external elements. The material at least partially encloses at least one of the first surface **204** of the PCB **202**, the battery **220**, and a portion of the electrical circuitry **250**. The material **212** defines an opening **214** through which the connection assembly **230** is accessible. In this manner, the external stimulator S can be physically coupled to the apparatus **200** via the connection assembly **230**, as illustrated in FIG. 6. The material **212** can be any suitable material including, for example, a foam, a water-proof material, plastic, an insulative material, a non-conductive material, a film, or the like, or any combination of the foregoing.

In use, a target bodily tissue is identified as the target for electrical stimulation. The apparatus **200** is positioned proximate to the identified target bodily tissue, such as on a surface of the patient's skin proximate to a subcutaneous target bodily tissue. For example, the apparatus **200** can be positioned proximate to an arm, leg, back, or other portion of the patient's body. The first and second electrodes **242**, **244** are adhered to the patient's skin in the desired position.

The external stimulator S is placed in electrical communication with the battery **220** of the apparatus **200**. The external stimulator S is electrically coupled to the battery **220** by coupling the external stimulator to the connectors **232**, **234**. The battery **220** provides power to the external stimulator S. In response to receiving power from the battery **220**, the external stimulator S generates an electrical current and transmits the electrical current to the apparatus **200** via at least one connector **232**, **234**, **236**. The electrical current is transmitted via the electrical circuitry **250** to the first electrode **242**. The first electrode **242** transmits at least a portion of the electrical current E through the bodily tissue of the patient, as illustrated in FIG. 7. In some embodiments, as illustrated in FIG. 8, a portion of the electrical current E transmitted from the first electrode **242** through the bodily tissue is picked by a proximal end portion of an electrical conductor L (or lead) at least partially implanted within the bodily tissue, as illustrated in FIG. 8. The electrical conductor L is configured to transmit a

portion of the electrical current E from its proximal end portion to a distal end portion of the electrical conductor L. The electrical current E is transmitted from the distal end portion of the electrical conductor L through the bodily tissue T to the second electrode **244**. At least a portion of the electrical current E is received by the second electrode **244**. The electrical circuitry **250** transmits the electrical current E to at least one of the battery **220** or the external stimulator S to complete one cycle of electrical stimulation of the target bodily tissue. The cycle of electrical stimulation of the target bodily tissue is repeated as necessary. The apparatus **200** is disposable and can be removed from the patient and discarded when it is no longer needed or suitable for treatment, such as, for example, when a prescribed course of treatment is completed or when the battery is exhausted.

Although the substrate **202** has been illustrated and described as being a PCB, in other embodiments, the substrate can be constructed of a different material. For example, the substrate can be constructed of silicon, polyamide, or another suitable polymer, or any combination of the foregoing.

Furthermore, although at least a portion of the electrical circuitry **250** and/or the connection assembly **230** has been illustrated and described as being a conductive ink printed on a surface of the substrate **202**, in other embodiments, at least one of the electrical circuitry and the connection assembly can be differently constructed. For example, the connection assembly can include a connector that is a wire, an antenna, a metal electrode, or the like. In another example, at least a portion of electrical circuitry can include or be a wire or another electrically conductive material.

Although the material **212** is illustrated as at least partially enclosing at least one of the first surface **204** of the PCB **202**, the battery **220**, and a portion of the electrical circuitry **250**, in other embodiments, a material can be disposed over a different portion of the apparatus **200**. For example, in some embodiments, the material can be an insulative film disposed over a portion of the electrical circuitry.

Although the apparatus **200** has been illustrated and described as being adhered to the body of the patient via adhesive gel electrodes, in other embodiments, an apparatus can be coupled to the patient with a tape, a strap, a band, a glue, or another adhesive, or any combination of the foregoing. Furthermore, an apparatus that includes a glue, another adhesive, or the like, to adhere to the patient can include the glue, other adhesive, or the like on all or a portion of the portion of the apparatus contacting the body of the patient.

Although the apparatus **200** has been illustrated and described as having a connection assembly **230** including a Y-shaped hydrophobic barrier **218**, in other embodiments, an apparatus can include a barrier having a different configuration. For example, as illustrated in FIG. 9A, in some embodiments, an apparatus **260** can include a barrier **268**, **269** disposed about at least a portion of at least one connector **264**, **266**. In another example, in some embodiments, as illustrated in FIG. 9B, an apparatus **270** can include a plurality of barriers **278**, **279** positioned at least on opposing sides of at least one connector **274**. In still another example, as illustrated in FIG. 9C, in some embodiments, an apparatus can include a non-Y-shaped barrier **288** positioned between at least a first connector **284** and a second connector **286**.

FIG. 10 is an illustration of an apparatus **300** according to an embodiment. The apparatus **300** is configured to transmit an electrical current from an external stimulator S<sub>2</sub> to a target bodily tissue. The apparatus includes a substrate **302**, a power source **320**, a connection assembly **330** including three con-

11

nectors 332, 334, 336, electrical circuitry 350 including a fuse 358, and an electrode assembly 340.

The substrate 302 includes a first layer 308 having a first surface 304 and a second layer 310 having a second surface 306 different than the first surface. As illustrated in FIG. 10, each of the power source 320, the connectors 332, 334, 336, and the electrical circuitry 350 is at least partially embedded in the first layer 308 of the substrate 302. The first layer 308 of the substrate is formed of a first material. The second layer 310 of the substrate is formed over a portion of the electrode assembly 350. The second layer 310 of the substrate is formed of a second material different than the first material.

As illustrated in FIG. 10, the apparatus 300 includes a magnet 366 coupled to the substrate 302. The magnet 366 is configured to move a switch in the external stimulator from a first position in which the switch is electrically coupled to a first output channel to a second position in which the switch is electrically coupled to a second output channel different than the first output channel. For example, as illustrated in FIG. 10, movement of the magnet 366 from its first position can move the switch from a first position in which the switch is coupled to a high output channel (indicated as ChH) to a second position in which the switch is coupled to a low output channel (indicated as ChL). In this manner, the magnet 366 can be used to control an amount of electrical current output from the external stimulator  $S_2$  to the apparatus 300.

Although the apparatus 200, 300 have been illustrated and described as including at first electrode 242, 342 and a second electrode 244, 344 disposed on a second surface 206, 306 of a substrate 202, 302 and configured to facilitate transmission of an electrical current from an external stimulator  $S_1$ ,  $S_2$  through the bodily tissue, in some embodiments, an apparatus is configured to deliver or transmit the electrical current to the bodily tissue in a different manner. For example, as illustrated in FIG. 11, an apparatus 400 according to an embodiment is an electrode-battery assembly configured for percutaneous delivery of an electrical current to target bodily tissue.

The electrode-battery assembly 400 includes a substrate 402, a battery 420, a connection assembly 430, electrical circuitry 450, and an electrode assembly 440. The substrate 402 has a first layer 408 and a second layer 410. The battery 420, and electrical circuitry 450 are at least partially embedded in the first layer 408 of the substrate. The electrical circuitry 450 includes a fuse 458 configured to open the electrical circuit in the presence of a threshold electrical load, as described above.

An external stimulator  $S_3$  is electrically coupled to the electrode-battery assembly 400 via the connection assembly 430. The connection assembly 430 includes a first connector 432, a second connector 434, a third connector 436, and a fourth connector 438. The connectors 432, 434, 436, 438 of the connection assembly 430 extend from a surface of the first layer 408 of the substrate 402.

The third connector 436 is configured to receive an electrical current input from the external stimulator  $S_3$ . The third connector 436 is configured to transmit the electrical current via a first electrical pathway 452 of the electrical circuitry 450 to the fourth connector 438. The fourth connector 438 is physically and electrically coupled to an electrode 446 of the electrode assembly 440 via a second electrical pathway 454. For example, as illustrated in FIG. 11, the fourth connector 438 is coupled to the second electrical pathway 454 including an electrical conductor exterior to the substrate 402 and extending from the fourth connector 438 to the electrode 446 implanted within the bodily tissue T.

The electrode assembly 440 includes a first electrode 442, a second electrode 444, and a third electrode 446. The first

12

electrode 442 and second electrode 444 are coupled to the second layer 410 of the substrate 402. The third electrode 446 is coupled to the substrate 402 via the second electrical pathway 454 and is configured to be at least partially implanted within the bodily tissue T. At least the third electrode 446 is configured to transmit an electrical current from the external stimulator  $S_3$  to the bodily tissue T. In use, the external stimulator  $S_3$  transmits an electrical current to the third connector 436. The electrical current is transmitted from the third connector 436 via the first electrical pathway 452 to the fourth connector 438, and from the fourth connector via the second electrical pathway 454 to the third electrode 446. The third electrode 446 transmits at least a portion of the electrical current E to the bodily tissue, as illustrated in FIG. 11. The second electrode 444 is configured to receive at least a portion of the electrical current from the bodily tissue.

The electrode-battery assembly 400 is configured to receive an electrical current from the external stimulator  $S_3$  via at least one of a first output channel and a second output channel of the external stimulator. For example, as illustrated in FIG. 11, the external stimulator  $S_3$  has a high output channel ChH and a low output channel ChL. The electrode-battery assembly 400 is illustrated in FIG. 11 as being electrically coupled to the low output channel ChL of the external stimulator  $S_3$  via the third connector 436, however, in use, a patient or practitioner operating the stimulator can selectively electrically couple the electrode-battery assembly to the high output channel ChH via the third connector.

The external stimulator  $S_3$  can be wirelessly controlled by the operator. For example, the operator can wirelessly control the external stimulator  $S_3$  using a remote control R to communicate with the stimulator over a radio frequency. In this manner, the operator can wirelessly program the external stimulator  $S_3$ , power on and/or off the external stimulator  $S_3$ , and/or select the desired output channel (e.g., ChH and/or ChL). In some embodiments, for example, the remote control R can be a dedicated programming device for use specifically with the stimulation system. In other embodiments, however, the remote control R can be a personal digital assistant (PDA) or other hand-held computing device that is configured to communicate with the external stimulator  $S_3$ . Such a PDA or hand-held computing device can include, for example, a Central Processing Unit (CPU) and electronic memory, and can be generally used for storing and organizing information and for providing tools for everyday tasks. In such embodiments, the system can include an adaptor and/or cradle (not shown) configured to be coupled to and/or receive the PDA. The adaptor and/or cradle can enable the PDA to communicate with the external stimulator  $S_3$  such that external stimulator  $S_3$  can be wirelessly controlled by the operator, patient or other user. Although described as including an adaptor and/or cradle, in other embodiments, the external stimulator  $S_3$  can be wirelessly controlled using a PDA and/or hand-held computing device without the need for an adaptor and/or cradle.

Although the apparatus 400 is illustrated and described as percutaneously transmitting the electrical current, in some embodiments, an apparatus is configured for both transcutaneous and percutaneous transmission of the electrical current. For example, an apparatus can be configured to transcutaneously transmit the electrical current through bodily tissue from a first electrode disposed on a surface of the patient's skin and percutaneously transmit the electrical current via a second electrode (e.g., similar to electrode 446 described above) at least partially implanted in the bodily tissue. In some embodiments, the high output channel ChH of the external stimulator is configured for transcutaneous stimulation and the low output channel ChL is configured for percu-

13

taneous stimulation of the target bodily tissue. Electrical current from each of the first electrode and the second electrode can be received by a third electrode disposed on the skin of the patient, similar to electrode 444 described above.

Although the apparatus 200, 300, 400 described above have been illustrated and described as including a fuse 258, 358, 458 configured to open the electrical circuit, in other embodiments, an apparatus 500 includes electrical circuitry differently configured to prevent a short circuit of the electrical circuit, as illustrated in FIG. 12. The apparatus 500 is configured to transmit an electrical stimulation to a bodily tissue and includes a substrate 502, an electrode assembly 540, a power source 520, and a connection assembly 530.

The substrate 502 has a first surface 504 and a second surface 506 different than the first surface. The power source 520 is coupled to the substrate 502 and can be any suitable source of power described herein. The power source 520 has a positive terminal 522 and a negative terminal 524. The power source 520 is configured to provide power to an external stimulator  $S_4$ , for example, when the external stimulator is in electrical communication with the power source.

The electrode assembly 540 is coupled to the second surface 506 of the substrate 502. The electrode assembly 540 is configured to facilitate transmission of an electrical current from the external stimulator  $S_4$  through the bodily tissue. The electrode assembly includes a first electrode 542 and a second electrode 544 different than the first electrode.

The connection assembly 530 is coupled to the substrate 502 and includes up to two connectors configured to be in electrical communication with the external stimulator  $S_4$ . Specifically, as illustrated in FIG. 12, the connection assembly 530 includes a first connector 532 and a second connector 534. Each of the first connector 532 and a second connector 534 is coupled to the first surface 504 of the substrate 502. The first connector 532 is configured to electrically couple the external stimulator  $S_4$  to the positive terminal 522 of the power source 520 and to the first electrode 542. The second connector 534 is configured to electrically couple the external stimulator  $S_4$  to the negative terminal 524 of the power source 520 and to the second electrode 544.

The connection assembly 530 has a first configuration in which the two connectors 532, 534 are electrically coupled to the external stimulator  $S_4$  (as illustrated in FIG. 12) and a second configuration in which the two connectors are electrically isolated from the external stimulator (not shown). When the connection assembly 530 is in its first configuration, the connection assembly completes a power circuit between the power source 520 and the external stimulator  $S_4$  and a stimulation circuit between the external stimulator and the electrode assembly 540, as described in more detail herein.

The power circuit includes electrical circuitry 550, a diode 562, the connection assembly 530, and the power source 520. As illustrated in FIG. 12, the electrical circuitry 550 includes a first electrical pathway 552 and a second electrical pathway 554, each coupled to the substrate 502. The first electrical pathway 552 electrically couples the first connector 532 to the positive terminal 522 of the power source 520. The second electrical pathway 554 electrically couples the second connector 534 to the negative terminal 524 of the power source 520. When the connection assembly 530 is in its second configuration, the power circuit is open (or incomplete). When the connection assembly 530 is in its first configuration such that the first and second connectors 532, 534, respectively, are electrically coupled to the external stimulator  $S_4$ , the power circuit is closed (or complete) and the power source 520 provides power to the external stimulator.

14

The diode 562 is coupled to the substrate 502 and is disposed within the first electrical pathway 552. The diode 562 is configured to allow electrical current to flow in a first direction and to substantially inhibit flow of the electrical current in a second direction different than the first direction. As illustrated in FIG. 12, the diode 562 is configured to allow flow of the electrical current from the power source in a first direction towards the first electrode 542 via the first electrical pathway 552. The diode 562 is configured to substantially inhibit flow of the electrical current in a second direction opposite the first direction, such as from the first connector 532 to the power source 520 and/or to the second electrode 544 via the first electrical pathway 552. In this manner, the diode 562 is configured to prevent a short circuit of the electrical circuit because the stimulating electrical current transmitted from the external stimulator  $S_4$  to the first connector 532 is substantially inhibited from flowing to the power source 520, which otherwise may cause the power source to overheat, explode, or otherwise become defective.

The stimulation circuit includes electrical circuitry 550, a capacitor 564, the connection assembly 530, and the electrode assembly 540. As illustrated in FIG. 12, the electrical circuitry 550 includes a third electrical pathway 556 coupled to the substrate 502. The third electrical pathway 556 electrically couples the first connector 532 to the first electrode 542 of the electrode assembly 540. The second electrical pathway 554 electrically couples the second connector 534 to the second electrode 544. As such, the negative terminal 524 of the power source 520 is also coupled to the second electrode 544.

The capacitor 564 is coupled to the substrate 502 and is disposed in the electrical circuitry 550, for example, in the third electrical pathway 556 as illustrated in FIG. 12. The capacitor 564 is configured to separate an alternating current from a direct current. The capacitor 564 is configured to substantially inhibit flow of the direct current from the power source 520 to the first electrode 542. The capacitor 564 is configured to deliver at least one of the alternating current and the direct current from the external stimulator to the first electrode.

When the connection assembly 530 is in its first configuration (and the power circuit is closed, as described above), the stimulation circuit is also closed and an electrical current can be transmitted from the external stimulator through the target bodily tissue via the apparatus 500. Specifically, the electrical current is transmitted from the external stimulator  $S_4$  to the first connector 532. The first connector 532 transmits the electrical current towards the first electrode 542 via the third electrical pathway 556. The capacitor 564 separates direct current from alternating current, and then transmits at least one of the direct current or the alternating current to the first electrode 542. The first electrode 542 transmits the electrical current through the bodily tissue T. The second electrode 544 receives at least a portion of the electrical current from the bodily tissue T and transmits the electrical current to the electrical circuitry 550 of the apparatus 500.

Although the diode 562 has been illustrated and described as being configured to allow flow of the electrical current from the power source 520 in a first direction towards the first electrode 542 and to substantially inhibit flow of the electrical current in a second direction opposite the first direction, such as from the first connector 532 to the power source 520 and/or to the second electrode 544 via the first electrical pathway 552, in some embodiments, the diode 562 is configured to allow flow of the electrical current in the second direction and to substantially inhibit flow of the electrical current in the first direction.

15

Although the apparatus **500** has been illustrated and described as being electrically coupled to the external stimulator via the two mechanical connectors **532**, **534**, in some embodiments, an apparatus is electrically coupled to the external stimulator in a different manner. For example, as illustrated in FIG. **13**, in some embodiments, an apparatus **600** is wirelessly electrically coupled to an external stimulator  $S_5$ .

The apparatus **600** includes a substrate **602** configured to be positioned on or proximate to the bodily tissue  $T$ . The substrate **602** has a first surface **604** and a second surface **606** different than the first surface. The second surface **606** of the substrate is configured to face the bodily tissue and the first surface **604** is configured to face away from the bodily tissue when the apparatus is positioned on or proximate to the bodily tissue. A power source **620** is coupled to the substrate **602**. As illustrated in FIG. **13**, the power source **620** is at least partially embedded in the substrate **602**.

The apparatus **600** includes a connection assembly **630** configured to be in electrical communication with an external stimulator  $S_5$ . The connection assembly **630** includes a first connector **632** and a second connector **634**. Each of the first connector **632** and the second connector **634** is an antenna configured as a first coil **614** and a second coil **616**, respectively, that is configured to be in wireless electrical communication with the external stimulator  $S_5$ . The first coil **614** and second coil **616** are each coupled to the first surface **604** of the substrate **602**. Specifically, the coils **614**, **616** are embedded in the substrate **602**. In this manner, the coils **614**, **616** are configured to prevent a short circuit of the electrical circuit, for example, by substantially preventing exposure of the coils to a fluid.

The connection assembly **630** has a first configuration in which the coils **614**, **616** are electrically coupled to the external stimulator  $S_5$  and a second configuration in which the coils are electrically isolated from the external stimulator. The connection assembly **630** is configured to complete a power circuit between the power source **620** and the external stimulator  $S_5$  and a stimulation circuit between the external stimulator and an electrode assembly **640**, as described in more detail herein.

As illustrated in FIG. **13**, the power circuit includes the first coil **614**, the power source **620**, an oscillator **638**, and electrical circuitry **650**. The electrical circuitry **650** includes a switch **660** disposed in a first electrical pathway **652**. The switch **660** can be any suitable switch for opening and closing a circuit. For example, the switch **660** can be a reed switch including a pair of contacts on ferrous metal reeds in a hermetically sealed glass envelope (not shown). The switch **660** has an open configuration (see, e.g., FIG. **13**) and a closed configuration. In its open configuration, the pair of contacts of the reeds is open (or separate). Thus, the electrical circuit is open when the switch is in its open configuration. The switch **660** is movable to its closed configuration by the introduction of a magnetic field, such as by placing a magnet  $M$  in the external stimulator  $S_5$  proximate to the switch. Specifically, the presence of the magnetic field causes the pair of contacts to close or otherwise come together. As such, the switch **660** is configured to close the electrical circuit when the switch is moved to its closed configuration. The switch **660** is biased to its open configuration. In this manner, the electrical circuitry is configured to prevent a short circuit of the electrical circuit.

The power source **620** is configured to transmit an electrical current to the electrical circuitry **650** when the connection assembly **630** is in its first configuration and the switch **660** is in its closed configuration. The electrical circuitry **650** is configured to transmit the electrical current to the oscillator

16

**638**. The oscillator **638** is configured to deliver at least one oscillation (of electrical current) to the first coil **614** to initiate wireless transmission of an electrical output from the first coil to the external stimulator  $S_5$ . The first coil **614** is configured to wirelessly transmit the electrical output to the external stimulator  $S_5$ , such as to a coil  $C_1$ . The coil  $C_1$  of the external stimulator  $S_5$  can transmit the electrical current to a source of power  $P_1$  disposed within the external stimulator. The source of power  $P_1$  can transmit the electrical current to a stimulation circuit and/or a radio frequency circuit coupled to the external stimulator  $S_5$ . For example, the source of power  $P_1$  can transmit the electrical current to a portion of the stimulation circuit  $P_2$  disposed on the external stimulator  $S_5$ .

As illustrated in FIG. **13**, the stimulation circuit includes the second coil **616**, electrical circuitry **650**, and an electrode assembly **640**. The second coil **616** is disposed proximate to the first surface **604** of the substrate **602**. Specifically, the second coil **616** is embedded in the substrate **602** proximate the first surface **604**. The second coil **616** is configured for wireless electrical communication between an electrode of the electrode assembly **640** and the external stimulator  $S_5$ . For example, the second coil **616** is configured to receive an electrical input from a coil  $C_2$  of the external stimulator  $S_5$  and to transmit at least a portion of the electrical input (or current) to the electrical circuitry **650**.

The electrical circuitry **650** is configured to transmit the electrical current to the electrode assembly, for example, via a second electrical pathway **654**. The electrode assembly **640** is coupled to the second surface **606** of the substrate **602** and includes a first electrode **642** and a second electrode **644** different than the first electrode. The first electrode **642** is coupled to the second electrical pathway **654** of the electrical circuitry **650**. The first electrode **642** can receive an electrical current from the electrical circuitry **650** via the second electrical pathway **654** and can facilitate transmission of the electrical current through the bodily tissue. The second electrode **644** is configured to receive a portion of the electrical current from the bodily tissue. The second electrode **644** is configured to transmit the electrical current to the electrical circuitry **650**, such as to a third electrical pathway **656**. The electrical circuitry **650** can transmit the electrical current to the second coil **616**. The second coil **616** can wirelessly transmit an electrical output to the external stimulator  $S_5$ .

Although the apparatus **600** is illustrated and described as being in wireless communication with the external stimulator  $S_5$  via a connection assembly **630** including the first and second coils **614**, **616**, respectively, in some embodiments, an apparatus is in wireless communication with an external stimulator via a connection assembly having a different configuration. For example, in some embodiments, an apparatus includes at least one antenna configured to wirelessly communicate with an external stimulator.

As illustrated in FIG. **14**, an apparatus **700** includes a connection assembly **730** having a plurality of connectors that includes a first connector **732**, a second connector **734**, and a third connector **736**. The connection assembly **730** is disposed proximate to a first surface **704** of a substrate **702**. Each of the first connector **732**, second connector **734**, and third connector **736** is configured to be coupled to a counterpart connector (not shown) on the stimulator  $S_6$ . The first connector **732** is configured to be in electrical communication with a battery **720** coupled to the substrate **702** via a first electrical pathway **752** of electrical circuitry **750**. The first electrical pathway **752** includes a first switch **712**. The second connector **734** is configured to be in electrical communication with the battery **720** via a second electrical pathway **754**. The second connector **734** is also configured to be in electrical

communication with a first electrode **744** of an electrode assembly **740** coupled to the substrate **702** via the second electrical pathway **754**. The electrode assembly **740** can be coupled, for example, to a second surface **706** of the substrate **702**. The second electrical pathway **754** includes a second switch **714**. The third connector **736** is configured to be in electrical communication with a second electrode **742** of the electrode assembly **740** via a third electrical pathway **756**. The third electrical pathway **756** includes a third switch **716**. Each switch **712**, **714**, **716** is configured to move from an open configuration to a closed configuration in the presence of a magnetic field. For example, as illustrated in FIG. **14**, each switch **712**, **714**, **716** is configured to move to its respective closed configuration by a magnet  $M_2$  coupled to the external stimulator  $S_6$ . When the switches **712**, **714**, **716** are each in the closed configuration, and the external stimulator  $S_6$  is in electrical communication with the connection assembly **730**, the electrical circuit is complete (or closed).

When the electrical circuit is complete, the battery **720** is configured to provide power to the external stimulator  $S_6$ . Power from the battery **720** enables the external stimulator to generate an electrical output to be received as an electrical input by the third connector **736**. The second electrode **742** is configured to receive the electrical current from the third connector **736** via the third electrical pathway **756**. The second electrode **742** is configured to transmit the electrical current through target bodily tissue **T**. The first electrode **744** is configured to receive at least a portion of the electrical current from the bodily tissue **T** and to transmit the electrical current to the external stimulator  $S_6$  via the second electrical pathway **754**.

Although the apparatus **600**, **700** have been illustrated and described as including two antenna coils **614**, **616** and three connectors **732**, **734**, **736**, respectively, in other embodiments an apparatus can include any suitable combination of connectors, e.g., wired and/or wireless, for electrical communication with an external stimulator.

In some embodiments, as illustrated in FIG. **15**, an apparatus **760** includes a planar dipole antenna **764** that is printed onto a substrate **762**, such as a PCB. The antenna **764** includes a first connector **766**, a first branch **767**, a second connector **768**, and a second branch **769**. The first connector **766** is configured to be in electrical communication with an external stimulator (not shown). The first branch **767** is configured to electrically couple the first connector **766** to electrical circuitry (not shown) coupled to the substrate **762**. The second connector **768** is configured to be in electrical communication with the external stimulator. The second branch **769** is configured to electrically couple the second connector **768** to the electrical circuitry.

In some embodiments, as illustrated in FIG. **16**, an apparatus **770** includes a planar folded dipole antenna coupled to a substrate **772**. The antenna **774** includes a first connector **776**, a first branch **777**, a second connector **778**, and a second branch **779**. The first connector **776** is configured to be in electrical communication with an external stimulator (not shown). The first branch **777** is configured to electrically couple the first connector **776** to electrical circuitry (not shown) coupled to the substrate **772**. The second connector **778** is configured to be in electrical communication with the external stimulator. The second branch **779** is configured to electrically couple the second connector **778** to the electrical circuitry.

In yet another example, in some embodiments, as illustrated in FIG. **17**, an apparatus **780** includes a planar non-symmetrical dipole antenna **784**, which may also be referred to as a monopole antenna, coupled to a substrate **782**. The

antenna **784** includes a first connector **786** and a branch **787**. The first connector **786** is configured to be in electrical communication with an external stimulator (not shown). The branch **787** is configured to electrically couple the first connector **786** and electrical circuitry (not shown) coupled to the substrate **782**. The branch **787** can be coupled to a power source **785**. The antenna **764** includes a second connector **788** configured to be in electrical communication with the external stimulator.

In still another example, in some embodiments, as illustrated in FIG. **18**, an apparatus **790** includes a planar spiral antenna **794** coupled to a substrate **792**, such as a PCB. The antenna **794** includes a first connector **796**, a second connector **798**, and an electrical pathway **797**. Each of the first connector **796** and the second connector **798** is configured to be in electrical communication with an external stimulator (not shown). The electrical pathway **797** electrically couples the first connector **796** to the second connector **798**. The electrical pathway **797** is configured as a spiral at least partially printed on a first surface **793** of the PCB **792**. In some embodiments, a return electrical pathway (not shown) can be at least partially printed on an opposing surface (not shown) of the PCB **792**. In some embodiments, a return electrical pathway can be at least partially printed on an inner layer of a multi-layered PCB.

Although the apparatus **200**, **300**, **400**, **500**, **600**, **700** have been illustrated and described as including a power source (or battery) **220**, **320**, **420**, **520**, **620**, **720**, respectively, coupled to a substrate **202**, **302**, **402**, **502**, **602**, **702**, respectively, in some embodiments, an apparatus includes a power source that is the substrate.

For example, as illustrated in FIG. **19**, an apparatus **800** includes a flexible battery **820** having a first surface **804** and a second surface **806**. The flexible battery **820** is configured to provide power to an external stimulator  $S_7$  coupled to the flexible battery **820**. The external stimulator  $S_7$  can be coupled to the flexible battery by any coupling mechanism described herein that puts the external stimulator in electrical communication with the apparatus **800**. For example, as illustrated in FIG. **19**, the apparatus **800** includes a connection assembly **830** coupled to the first surface of the flexible battery **820**. The connection assembly **830** is configured to complete a power circuit between the flexible battery **820** and the external stimulator  $S_7$  and a stimulation circuit between the external stimulator and at least one electrode. The connection assembly **830** includes a first connector **832** and a second connector **834**. Each connector **832**, **834** is configured to electrically couple the flexible battery **820** to the external stimulator  $S_7$ . The first connector **832** is configured to electrically couple the external stimulator  $S_7$  to a first electrode **842** of an electrode assembly **840** via electrical circuitry **850**. The second connector **834** is configured to electrically couple the external stimulator  $S_7$  to a second electrode **844** of the electrode assembly via the electrical circuitry **850**. The electrode assembly **840** is coupled directly to the second surface **806** of the flexible battery **820**. Each of the first electrode **842** and the second electrode **844** is configured to contact a bodily tissue.

In use, when the external stimulator  $S_7$  is electrically coupled to the flexible battery **820**, the flexible battery provides power to the external stimulator. The external stimulator  $S_7$  transmits an electrical output to the first connector **832**. The first connector **832** transmits the electrical input as an electrical current to the first electrode **842** via a first electrical pathway **852**. The first electrode **842** transmits the electrical current through the bodily tissue to stimulate at least a portion of the bodily tissue. The second electrode **844** receives a portion of the electrical current from the bodily tissue. The

second electrode **844** transmits the electrical current to the second connector **834** via a second electrical pathway **854**. The second connector **834** transmits an electrical output to the external stimulator  $S_7$ .

The flexible battery **820** can be biodegradable. In some embodiments, for example, the flexible battery **820** can include a plurality of carbon nanotubes, cellulose disposed between at least a portion of a first carbon nanotube and a second carbon nanotube, an electrolyte, and/or a metal foil of lithium and ion.

While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Elements of each embodiment described herein may be combined in any suitable manner with one or more elements of another embodiment described herein. Where methods described above indicate certain events occurring in certain order, the ordering of certain events may be modified. Additionally, certain of the events may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.

For example, although apparatus **200** is illustrated and described as including a fuse **258**, in some embodiments, an apparatus similar to apparatus **200** may include a switch similar to switch **660** in addition to or instead of a fuse.

Although an apparatus has been illustrated and described herein as including one switch or three switches, in other embodiments, an apparatus can include any suitable number of switches, such as two, four, or more switches.

Although a switch has been illustrated and described herein as being in an open configuration in the absence of a magnetic field and as being in a closed configuration in the presence of a magnetic field, in other embodiments, the switch can be differently configured. For example, in some embodiments, a switch can be configured to be in a closed configuration in the absence of a magnetic field and an open configuration in the presence of a magnetic field.

In another example, although an apparatus has been illustrated and described herein as having mechanical connectors for connection to the external stimulator, in other embodiments, such an apparatus can include a wireless connector.

In still another example, although the apparatus have been illustrated and described as including two electrodes, in other embodiments, an apparatus can include any suitable number of electrodes. For example, in some embodiments, an apparatus includes a first cathodic electrode and a plurality of anodic electrodes. The plurality of anodic electrodes can include two, three, four, or more electrodes. Each electrode of the plurality of anodic electrodes can be selectively positioned at a desired location on the body of the patient, such as at spaced locations to help direct an electrical current from the cathodic electrode through a greater area of bodily tissue. In other embodiments, for example, an apparatus can include a first anodic electrode and a plurality of cathodic electrodes. The plurality of cathodic electrodes can transmit a plurality of electrical currents through the bodily tissue to the anodic electrode. In still other embodiments, an apparatus can include a plurality of cathodic electrodes and a plurality of cathodic electrodes.

Although the apparatus have been illustrated and described as including a substrate having a length and a width greater than a length of a first diameter of the power source and a width of a second diameter of the power source, in other embodiments, an apparatus includes a substrate having a different configuration. For example, as illustrated in FIG. 20, an apparatus **301** can include a substrate **303** that has a first portion **305** having a width  $W_1$  equal to or greater than a

diameter  $D$  of the power source **321** and a second portion **307** having a width  $W_2$  less than the width  $W_1$  of the first portion **305** of the substrate **303**.

In yet another example, although the connectors **232**, **234**, **236** of apparatus **200** have been illustrated and described as having a vertical orientation, in other embodiments, an apparatus can include at least one connector having a different orientation. For example, as illustrated in FIGS. 21-24, an apparatus **900** includes a substrate **902**, a power source **920**, a connection assembly **930**, electronic circuitry **950**, an electrode assembly **940**, and a coupling mechanism **912** (not shown in FIGS. 21 and 22 for clarity of illustration purposes).

The connection assembly **930** includes connectors **932**, **934**, **936**, **938**. Each of the connectors **932**, **934**, **936**, and **938** has a horizontal orientation. In other words, each of the connectors **932**, **934**, **936**, and **938** has an orientation that is substantially parallel to a portion of the substrate **902**. In this manner, the external stimulator  $S_8$  is moved laterally to engage and/or disengage with the connectors **932**, **934**, **936**, **938** of the apparatus **900**.

The connectors **932**, **934**, **936**, **938** are electrically coupled to an electrical pathway **952**, **954**, **956**, **958**, respectively, of the electronic circuitry **950**. The connectors **932**, **934**, **936**, **938** are configured to electrically couple the electronic circuitry **950** to the external stimulator  $S_8$  by being coupled to a counterpart connector  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ , respectively, of the external stimulator  $S_8$  (see, e.g., FIG. 23).

The coupling mechanism **912** is configured to couple the external stimulator  $S_8$  to the apparatus **900**. As illustrated in FIG. 24, the coupling mechanism **912** is configured to engage a portion of the external stimulator  $S_8$ . For example, the external stimulator  $S_8$  can define a groove or recess configured to receive a portion of the first member of the apparatus **900**. Although the apparatus **900** is illustrated as having the connection assembly **930** coupled to an end of the external stimulator  $S_8$  and the coupling mechanism **912** engaged with an opposite end of the external stimulator  $S_8$ , in other embodiments, the connection assembly and/or the coupling mechanism can engage a different portion of the external stimulator  $S_8$ .

Additionally, although apparatus **200** is shown and described herein as including a power source **220** that is coupled to the PCB **202** by electrically conductive tabs **226**, **228**, in other embodiments, the power source can be electrically coupled to the substrate in any suitable manner. For example, as illustrated in FIGS. 21-22, a portion **903** of the substrate **902** can be folded or otherwise disposed about a portion of the power source **920**. As also illustrated in FIG. 22, a portion of the electrical pathway **954** can be disposed on the portion **903** of the substrate **902** that is folded or otherwise disposed about the portion of the power source **920**. When the portion **903** of the substrate **902** is folded about the power source **920**, the portion of the electrical pathway **954** contacts the power source **920**. In this manner, a terminal of the power source **920** can be electrically coupled to the PCB **202** by the electrical pathway **954**.

In some embodiments, as illustrated in FIGS. 25 and 26, an apparatus **901** includes a housing **913**. The housing **913** is configured to at least partially enclose components (e.g., as shown dashed lines in FIG. 25) of the apparatus **901**, such as, but not limited to, a power source, electronic circuitry, a substrate, or the like. The housing **913** defines a perimeter **915** and a recess **917** within the perimeter **915**. The recess **917** is configured to at least partially receive an external stimulator  $S_9$ , as illustrated in FIG. 26. A coupling mechanism **909** (a portion of which is shown in dashed lines in FIG. 25) is configured to removably couple the external stimulator  $S_9$  to

21

the housing **913**. The coupling mechanism **909** is coupled to the housing **913** and includes a protrusion **911**. The protrusion **911** is configured to engage the external stimulator  $S_9$  when the external stimulator  $S_9$  is at least partially received in the recess **917**. The protrusion **911** is configured to release the external stimulator  $S_9$  when the protrusion **911** is pushed, depressed, or otherwise moved by the operator (e.g., a physician or the patient). In some embodiments, the protrusion **911** is configured to move the external stimulator  $S_9$  in a direction away from the recess **917** when the protrusion **911** is pressed or moved by the operator.

Although the apparatus **900** is illustrated and described herein as including four horizontally oriented connectors **932**, **934**, **936**, **938** configured to be coupled to the external stimulator  $S_8$ , in other embodiments, an apparatus **921**, **931** can be configured to receive a horizontal protrusion of an external stimulator  $S_{10}$ ,  $S_{11}$ , respectively, as illustrated in FIGS. **27** and **28**.

In another embodiment, as illustrated in FIG. **29**, an apparatus **941** includes a receiving portion **943** configured to receive a portion of an external stimulator  $S_{12}$  (not shown) and a protrusion **945** configured to engage an outer surface of the external stimulator  $S_{12}$ . In still another embodiment, an apparatus **951** is configured to be coupled to an external stimulator  $S_{12}$  without such a protrusion, as illustrated in FIG. **30**.

Although the apparatus **901** has been illustrated and described herein as including a housing **913** having a certain outer shape and/or profile, in other embodiments, an apparatus can have a different outer shape and/or profile. For example, an apparatus can include a housing having an outer shape and/or profile like that of apparatus **961**, **971**, and/or **981**, as illustrated in FIGS. **31-33**.

Although various embodiments for transmitting an electrical current or stimulation from an electronic device or stimulator to a bodily tissue have been described herein, additional embodiments are contemplated. For example, FIGS. **34-35** show a portion **170** of a stimulation system according to an embodiment. The stimulation system can be any of the stimulation systems shown and described herein, and is configured to transmit an electrical signal or stimulus from a detachable electronic device (not shown) to a bodily tissue of a patient. The portion **170** of the stimulation system can be, for example, a portion of an electrode-battery assembly. In another example, the portion **170** of the stimulation system can be a portion of an electrode base assembly.

The portion **170** of the stimulation system includes a base **172** and a substrate **180**. The base **172** is substantially rigid. An object with substantial rigidity can be characterized as having resistance to deflection and/or deformation in the presence of an external force (e.g., a bending force). The rigidity of an object is an extensive property of the object being described, and thus is dependent upon the material from which the object is formed and certain physical characteristics of the object (e.g., shape and boundary conditions). For example, the rigidity of an object can be increased or decreased by constructing the object from a material having a high modulus of elasticity. The modulus of elasticity is an intensive property of the constituent material and describes an object's tendency to elastically (i.e., non-permanently) deform in response to an applied force. In another example, the rigidity of the object can be increased or decreased by changing the flexural modulus of a material of which the object is constructed. Flexural modulus is used to describe the ratio of the applied stress on an object in flexure to the corresponding strain in the outermost portions of the object. The flexural modulus, rather than the modulus of elasticity, is used to characterize certain materials, for example plastics, that do

22

not have material properties that are substantially linear over a range of conditions. In some embodiments, the base **172** can be constructed from a material having a flexural modulus of at least 750,000 p.s.i.

The base **172** includes a first protrusion **174** and a second protrusion **176**. The base **172** is configured to be coupled to the electronic device (not shown in FIGS. **34** and **35**). For example, the base **172** can receive at least a portion of the electronic device within the region **175** between the first protrusion **174** and the second protrusion **176**. At least one of the first protrusion **174** and the second protrusion **176** can be configured to engage the electronic device when the portion of the electronic device is received by the base **172** (e.g., in a similar manner as described above with respect to protrusion **911** of apparatus **901**). The electronic device can be any suitable device including, for example, a stimulator, an external pulse generator, or other electronic device shown and described herein.

The substrate **180** is flexible and is coupled to the base **172**. Similarly stated, the substrate **180** has a low resistance to deflection, deformation and/or displacement when exposed to an external force. In this manner, the substrate **180** can be coupled to the base **172** such that the substrate **180** substantially conforms to the shape of one or more portions of the base **172** (e.g., the first protrusion **174**). As described herein, this arrangement allows the substrate **180** to be wrapped, woven, and/or otherwise positioned relative to the base **172** in a flexible manner.

The flexibility of the substrate **180** is an extensive property, and thus is dependent upon the properties of the material from which the substrate **180** is constructed as well as certain physical characteristics of the substrate **180** (e.g., shape). For example, the flexibility of the substrate **180** can be increased by constructing the substrate **180** from a material having a low modulus of elasticity and/or a low flexural modulus. In some embodiments the substrate **180** can have a modulus of elasticity and/or a flexural modulus of less than approximately 750,000 p.s.i. In other embodiments the substrate **180** can have a modulus of elasticity and/or a flexural modulus of less than approximately 400,000 p.s.i.

The flexibility of the substrate **180** can also be increased or decreased by changing the shape, cross-sectional area and/or thickness of the substrate **180**. Although the substrate **180** is shown as being substantially planar and having a substantially constant thickness, in other embodiments, the substrate **180** can have a non-uniform thickness and/or can have an irregular cross-sectional shape (e.g., corrugations or the like) to result in the desired flexibility. Additionally, to increase the flexibility, the substrate **180** can be thin. In some embodiments, for example, the substrate **180** can have a thickness of approximately 50 to approximately 120 microns (approximately 0.002 to approximately 0.005 inches) or less.

In some embodiments, the substrate **180** can be a polymer, such as a polyester film, a polyimide film, or the like. Such polymers can also include, for example, Mylar®, Kapton® or the like. In other embodiments, the substrate **180** can be a reinforced polymer that includes, for example, a polymer reinforced with glass fibers, graphite fibers, or the like. Such materials can provide the electrical properties (e.g., resistivity and/or conductivity) and the mechanical properties (e.g., toughness, tear resistance, or the like) desired.

The substrate **180** has a first surface **181** and a second surface **182**. As shown in FIGS. **34-35**, the substrate **180** is coupled to the base **172** such that a first portion of the second surface **182** is in contact with the first protrusion **174**. A second portion of the second surface **182** is non-parallel to the first protrusion **174**. Said another way, when the substrate **180**



23

is coupled to the base 172, a portion of the substrate 180 is wrapped and/or woven about the first protrusion 174. Similarly stated, when the substrate 180 is coupled to the base 172, a portion of the substrate 180 is non-planar. The flexibility of the substrate 180 facilitates coupling of the substrate to the base 172 such that the substrate 180 is partially disposed about the first protrusion 174.

The substrate 180 includes an electrical circuit 185. The electrical circuit 185 is configured to electronically couple the electronic device to at least one of an electrode, a battery, or an antenna (not shown in FIGS. 34-35). In this manner, for example, the electrode can receive an electrical signal or stimulation from the electronic device via the electrical circuit 185. Also in this manner, the battery can provide power to the electronic device via the electrical circuit 185, for example, to provide sufficient power to the electronic device for the electronic device to generate an electrical signal or stimulation. In another example, the electrical circuit 185 can include the antenna (e.g., an antenna similar to at least one of antennae 614, 616, 764, 774, 784, 794), which can be in wireless electrical communication with the electronic device. In some embodiments, at least one of the electrode, battery, or antenna is coupled to or otherwise disposed on the substrate 180.

FIGS. 36-38 show a portion of a stimulation system 370 according to an embodiment. The stimulation system can be configured for use with a system to transmit an electrical signal from an electronic device (not shown) to a bodily tissue of a patient. The electronic device can be any suitable electronic device for producing an electrical signal, including any of the electronic devices shown and described herein.

The portion of the stimulation system 370 includes a substantially rigid base 372 and a flexible substrate 380. The flexibility of the substrate 380 facilitates conformance of the substrate 380 to portions of the base 372 and/or to a curvature of a body of the patient. Because the base 372 is substantially rigid, the base is configured to provide structural support to the substrate 380 when the substrate 380 is coupled to the base. The base 372 also has sufficient structural integrity to couple the electronic device to the portion of the stimulation system 370 and/or support the electronic device relative to the stimulation system.

The base 372 includes a first protrusion 374 and a second protrusion 376. The first protrusion 374 and the second protrusion 376 of the base 372 are each configured to maintain contact (e.g., electrical and/or physical contact) between the electronic device and at least the portion the stimulation system 370. For example, at least a portion of the electronic device can be received between the first protrusion 374 and the second protrusion 376 of the base 372. In some embodiments, for example, the first protrusion 374 and the second protrusion 376 are configured to be positioned adjacent a first end portion and a second end portion, respectively, of the electronic device when the electronic device is received between the first protrusion 374 and the second protrusion 376. In some embodiments, the first protrusion 374 and the second protrusion 376 collectively define an interference fit and/or a “snap fit” with the electronic device when the electronic device is received between the first protrusion 374 and the second protrusion 376. In this manner, the first protrusion 374 and/or the second protrusion 376 limit the movement of the electronic device relative to the base 372 when the electronic device is coupled to the base 372. In some embodiments, for example, the first protrusion 374 and/or the second protrusion 376 are configured to matingly engage (e.g., via a tab, recess, detent or the like) a portion of the electronic device. In some embodiments, the second protrusion 376 is

24

engaged with an end of the electronic device when the electronic device is coupled to the base 372 (e.g., as shown and described herein with respect to protrusion 911 of apparatus 901).

The base 372 defines a set of slots including a first slot 371, a second slot 373, and a third slot 375, each being different than the others. Similarly stated, the base 372 defines a series of elongated openings 371, 373, 375 that are distinct and/or non contiguous from each other. In other embodiments, however, the first slot 371, the second slot 373 and/or the third slot 375 can be contiguous and/or can share at least a portion of a common boundary. The first slot 371, the second slot 373 and the third slot 375 each receive a portion of the flexible substrate 380 when the flexible substrate 380 is coupled to the base 372. Similarly stated, the flexible substrate 380 is woven within the first slot 371, the second slot 373 and the third slot 375. More particularly, at least a first portion of the substrate 380 is disposed within the first slot 371 defined by the base, and at least a second portion of the substrate is disposed within the second slot 373 defined by the base, as illustrated in FIGS. 36-37.

The arrangement of the flexible substrate 380 within the first slot 371, the second slot 373 and the third slot 375 results in at least a portion of the flexible substrate 380 being wrapped about the first protrusion 374 of the base 372. In some embodiments, disposal of the substrate 380 within at least one of the slots 371, 373, 375 of the base 380 also serves to couple the substrate to the base 372. Moreover, the arrangement of the flexible substrate 380 within the first slot 371, the second slot 373 and the third slot 375 can be used to index and/or position the substrate 380 relative to the first protrusion 374 in a predetermined position. In this manner, as described in more detail below, a portion of the electrical circuit 385 included within the substrate 380 can be placed in electrical and/or physical contact with the electronic device.

The substrate 380 has a first surface 381 (e.g., an “upper surface”) and a second surface 382 (e.g., a “lower surface”). The substrate 380 is coupled to the base 372 such that a first portion 383 of the second surface 382 of the substrate is in contact with the first protrusion 374 of the base. When the substrate 380 is coupled to the base 372, a second portion 384 of the second surface 382 of the substrate 380 is non-parallel to the first portion 383 of the substrate, as illustrated in FIGS. 36-37. For example, in some embodiments, the first portion 383 of the second surface 382 of the substrate 380 is substantially perpendicular to the second portion 384 of the second surface of the substrate 380 when the substrate 380 is coupled to the base 372.

The substrate 380 includes an electrical circuit 385. The electrical circuit 385 can include, for example, any suitable electrical components, via, conductors and/or the like interconnected to perform the functions described herein. More particularly, the electrical circuit 385 includes electrical pathways 387, 386, 389. The electrical pathways can be, for example, conductive traces or metallic strips disposed on the flexible substrate 380. At least a portion of the electrical circuit 385 is included on the first surface 381 of the substrate 380, and is configured to be in electrical communication with the electronic device. For example, the portion of the electrical circuit 385 on the first surface 381 can be complementary to (e.g., on the opposite side of the substrate 380 from) the first portion 383 of the second surface 382 of the substrate 380, such that the portion of the electrical circuit 385 is at least partially disposed about the first protrusion 374 of the base 372. In this manner, for example, the portion of the electrical circuit 385 can be engaged with and/or disposed proximate to an end of the electronic device when the electronic device is



25

coupled to the base 372. When the portion of the electrical circuit 385 is engaged with and/or disposed proximate to an end of the electronic device, the electrical circuit 385 can electrically communicate with the electronic device in any manner described herein, including via wired and/or wireless electrical communication.

The electrical circuit 385 is configured to electronically couple the electronic device to at least one of an electrode, a battery, or an antenna. For example, as illustrated in FIG. 38, the electrical circuit 385 can electronically couple the electronic device to a battery 394 via at least one electrical pathway 387, 389 when the electronic device is coupled to the base 372. More particularly, the battery 394 can be coupled to the first surface 381 of the flexible substrate 380 such that a portion of the electrical pathway 387 is electrically coupled to a first terminal of the battery 394 and a portion of the electrical pathway 389 is coupled to a second terminal of the battery 394. In particular, the portion of the electrical pathway 389 is coupled to a second terminal of the battery 394 by a connector and/or tab similar to the conductive tabs 226, 228 shown and described above. Corresponding terminals of the electronic device (not shown in FIGS. 36-38) are also placed in electrical communication with the electrical pathways 387, 389 when the electronic device is coupled to the base 372 to complete the electronic connection. In this manner, the battery 394 can provide power to the electronic device via the electrical circuit 385 when the electronic device is coupled to the base 372.

The battery 394 can be any suitable battery, such as, for example, a Zinc-Air battery, a Silver-Oxide battery, a Lithium coin battery, a Lithium ion rechargeable battery and/or the like. In embodiments that include a rechargeable battery, the electronic device can be a recharging unit, and can be configured to supply power to the battery 394 via the electrical circuit 385 when the electronic device is coupled to the base 372. Although stimulation system 370 is illustrated and described as including a battery 394, in other embodiments, the stimulation system can include a different source of power, including any source of power shown and described herein.

As illustrated in FIG. 37, the electrical circuit 385 can electronically couple the electronic device to an electrode 392 via an electrical pathway 386. In use, an electrical signal or stimulus can be transmitted from the electronic device through the electrical pathway 386 to the electrode 392. In addition to the electrode 392, the electrical signal or stimulus can be transmitted via the electrical circuit 385 to at least one hydrogel electrode 397, 399 coupled to the second surface 382 of the substrate 380. More particularly, the electrical circuit 385 can electronically couple the electronic device to the hydrogel electrodes 397, 399 (illustrated in FIG. 38), such as via electrical pathway 388 or via electrical pathway 386 and electrode 392, respectively.

At least a portion of the substrate 380 also includes a conductive region 398 and a plurality of non-conductive regions 396. In particular, as illustrated in FIG. 37, the second surface 382 of the substrate 380 can include at least one of the conductive region 398 and the plurality of non-conductive regions 396. For example, at least one of the conductive region 398 and/or the plurality of non-conductive regions 396 can be disposed on the second surface 382 of the substrate 380. As described herein, this arrangement facilitates both the mechanical and electrical coupling of the hydrogel electrode 397 and/or the hydrogel electrode 399 to the substrate 380. In particular, as shown in FIGS. 37 and 38, the conductive and non-conductive regions 398, 396 are configured to contact the hydrogel electrode 397. The conductive region 398 is in elec-

26

trical communication with the electrical circuit 385, e.g., via the electrical pathway 388. As such, the conductive region 398 is configured to transmit an electrical signal or stimulus from the electrical circuit 385 to the hydrogel electrode 397. In other embodiments, the substrate 380 can include more than one conductive region 398 and plurality of non-conductive regions. For example, in some embodiments, the substrate can include a second conductive region (not shown) and a second plurality of non-conductive regions (not shown) configured to place the hydrogel electrode 399 in electrical communication with the electrical circuit 385, e.g., via the electrical pathway 386.

In some embodiments, the plurality of non-conductive regions 396 is included within and/or adjacent the conductive region 398. For example, the plurality of non-conductive regions 396 can be disposed on a surface of the conductive region 398. Each non-conductive region of the plurality of non-conductive regions 396 is discrete from the other non-conductive regions of the plurality. At least one non-conductive region of the plurality of non-conductive regions 396 extends beyond (or away from) a surface of the conductive region 398. Said another way, at least one non-conductive region of the plurality of non-conductive regions 396 is substantially non-planar with the conductive region 398. Said yet another way, at least one non-conductive region of the plurality of non-conductive regions 396 forms a surface textured area on the conductive region 398 of the substrate 380. In this manner, when the hydrogel electrode 397 is in contact with the substrate 380, the plurality of non-conductive regions 396 and the conductive region 398 collectively reduce the likelihood that the hydrogel electrode 397 will peel or otherwise move away from the conductive region 398 of the substrate 380 (e.g., in the presence of shearing forces). As such, the plurality of non-conductive regions 396 is configured to facilitate coupling and/or the mechanical connection, between the hydrogel electrode 397 and the substrate 380. Said another way, the plurality of non-conductive regions 396 is configured to facilitate retention of the hydrogel electrode 397 with respect to the conductive region 398 of the substrate 380.

Further, because each discrete non-conductive region of the plurality 396 is surrounded on its perimeter by the conductive region 398, an electrical current can be evenly distributed through the hydrogel electrode 397. Even distribution of the electrical current from the conductive region 398 of the substrate 380 through the hydrogel electrode 397 can reduce and/or prevent electrical "hotspots" (i.e., areas of concentrated electrical stimulation that can cause skin irritation and/or uncomfortable sensations to a patient).

The plurality of non-conductive regions 396 can be formed in any suitable manner. For example, in some embodiments, at least one non-conductive region of the plurality of non-conductive regions 396 is a solder mask. Use of a solder mask to form the plurality of non-conductive regions 396 on the conductive region 398 permits the plurality of non-conductive regions to be formed in any suitable desired pattern on the conductive region 398. Any known suitable method and/or material for producing the solder mask may be used. In another example, at least one non-conductive region is formed by a coating applied to the surface of the conductive region 398.

Although the plurality of non-conductive regions 396 have been described herein as being disposed on the conductive region 398 of the substrate 380, in other embodiments, the plurality of non-conductive regions can be included within and/or adjacent the conductive region in any suitable manner. For example, at least one non-conductive region of the plu-

rality of non-conductive regions can be a cavity or other depressed portion formed in a surface of the conductive region of the substrate. The cavity can be configured to receive a portion of the hydrogel electrode, thereby facilitating retention of the hydrogel electrode with respect to the conductive region of the substrate. In some embodiments, the cavity is formed by etching one or more discrete portions of the conductive region. For example, in some embodiments, the conductive region includes a metal layer disposed on or otherwise coupled to the substrate and the plurality of non-conductive regions is formed by etching away discrete portions of the metal layer. In another example, at least one non-conductive region of the plurality of non-conductive regions can be an aperture or other opening defined by the conductive region of the substrate. Such an aperture or other opening can be formed, for example, by punching the aperture or other opening in the conductive region of the substrate with a mechanical punch. The aperture can be configured to receive a portion of the hydrogel electrode, thereby facilitating retention of the hydrogel electrode with respect to the conductive region of the substrate. Although various manners for forming the non-conductive regions have been described herein, the plurality of non-conductive regions can be formed in any suitable manner, including any combination of the foregoing manners.

Each non-conductive region of the plurality of non-conductive regions **396** can be of any suitable size and/or shape. For example, as illustrated in FIG. 37, at least one non-conductive region of the plurality of non-conductive regions **396** can be in the shape of square (or a three-dimensional cube). The at least one non-conductive region can be, for example, a 1 mm×1 mm square. In other embodiments, at least one non-conductive region can be rectangular, triangular, oval, circular, or any other suitable shape. Additionally, the at least one non-conductive region can have dimensions of a size different than 1 mm×1 mm, such as a length, width, and/or cross-sectional diameter of greater than approximately 1 mm (e.g., approximately 2 mm to approximately 4 mm) or less than approximately 1 mm (e.g., approximately 0.3 mm to approximately 0.8 mm).

Although the portion of the substrate **380** including the conductive region **398** and the plurality of non-conductive regions **396** is illustrated and described as having a substantially circular shape, in other embodiments, the portion of the substrate can have any suitable shape. For example, in some embodiments, the portion of the substrate can be oval, rectangular, square, or another suitable shape.

Additionally, the portion of the substrate **380** including the conductive region **398** and plurality of non-conductive regions **396** can be of any suitable size. For example, the portion of the substrate **380** can have a diameter of approximately 30 mm. In another embodiments, the portion of the substrate can have a diameter of less than 30 mm (e.g., a diameter within the range of approximately 10 mm to approximately 30 mm). In still other embodiments, the portion of the substrate can have a diameter of greater than 30 mm (e.g., a diameter within the range of approximately 30 mm to approximately 60 mm).

The substrate **380** can be constructed of any suitable material. In some embodiments, for example, the substrate **380** is a flexible PCB. In another example, the substrate can be constructed of a different material, including silicon, polyamide, or another suitable polymer, or any combination of the foregoing.

Although stimulation system **370** is illustrated and described as having one portion of the substrate **380** including the conductive region **398** and the plurality of non-conductive

regions **396** associated with the hydrogel electrode **397**, in other embodiments, an apparatus can include more than one conductive region and more than one plurality of non-conductive regions. For example, in other embodiments, the substrate can include a number of conductive region and a number of non-conductive regions corresponding to, or equivalent to, the number of hydrogel electrodes to be utilized with the apparatus (e.g., two, three, or more).

FIGS. 39-42 show portions of a stimulator assembly **495** according to an embodiment. In particular, the stimulator assembly **495** includes a battery **494**, an electrode **497**, a stimulus generator **490**, a substrate **480**, a base **472** and a housing **465**. The stimulator assembly **495** can be used to transmit an electrical current from the stimulus generator **490** to a bodily tissue of a patient. Components of the stimulator assembly **495** can be similar in many respects to components of apparatus shown and described herein (e.g., components of electrode-battery assembly **100**, apparatus **200**, stimulation system **370**, **570**).

The housing **465**, which is a substantially flexible housing, is configured to be disposed about at least a portion of a stimulator assembly **495** (e.g., the base **472**). Similarly stated, the housing **465** has a low resistance to deflection, deformation and/or displacement when exposed to an external force. In this manner, the housing **465** can be disposed about other portions of the stimulator assembly **495** such that the housing **465** substantially conforms to the shape of one or more of the other portions of the stimulator assembly (e.g., the protrusion **476**, the stimulus generator **490**, or the like). In some embodiments, the flexible housing **465** is configured to substantially prevent access of moisture to the portion of the stimulator assembly **495** about which the flexible housing **465** is disposed.

The flexible housing **465** includes a receiving portion **466**, which is configured to receive at least a portion of the stimulus generator **490**. The receiving portion **466** defines a first opening **468** (see FIG. 40) and a second opening **469** (see FIG. 39) different than the first opening. The first opening **468** is configured to receive a protrusion **491** of the stimulus generator **490**. The protrusion **491** of the stimulus generator **490** can include, for example, one or more electrical contacts **493** configured to place the stimulus generator **490** in electrical communication with other portions of the stimulator assembly **495** (e.g., the battery **494**, the electrode **497**). The electrical contacts **493** can be any suitable mechanism for electrically coupling the stimulus generator **490** with other portions of the stimulator assembly **495**. In some embodiments, the electrical contacts **493** are biased to help retain the stimulus generator **490** to the housing **465** and/or the stimulator assembly **495**. For example, the electrical contacts **493** can include a spring, which may also be configured to transmit an electrical current between the stimulus generator **490** and the stimulator assembly **495**, an elastomer, or other suitable biasing mechanism, or any combination of the foregoing.

The second opening **469** of the flexible housing **465** is configured to receive a protrusion **476** of the base **472**. The base **472** can be similar to the base **372** and/or the base **172** shown and described above. As described in more detail herein, the protrusion **476** of the base **472** is configured to couple the stimulus generator **490** to the housing **465** and other components of the stimulator assembly **495**. Although the first and second openings **468**, **469** of the housing **465** are illustrated as being defined by opposing ends of the receiving portion **466**, in other embodiments, the first opening and/or the second opening can be defined by a different portion of the receiving portion.

As shown in FIG. 42, the housing 465 also defines a recess 464 configured to receive a fastening member 474 (shown in FIG. 39) of the base 472. A portion of the housing 465 has been removed in FIG. 42 for illustrative purposes only. The fastening member 474 can include end portions 475, 475', each of which are configured to be received in respective openings 467, 467' defined by the housing 465. The end portions 475, 475' are each configured to facilitate coupling of the housing 465 to the stimulator assembly 495 when the end portions 475, 475' are received in the openings 467, 467'. As such, when the flexible housing 465 is disposed about at least a portion of the stimulator assembly 495 and the fastening member 474 is received in the recess 464, as illustrated in FIG. 40, movement of the housing 465 relative to other portions of the stimulator assembly 495 is limited. In other words, the fastening member 474 is configured to couple or fasten the housing 465 to the other portions of the stimulator assembly 495 in a manner such that the lateral and/or vertical movement of the housing 465 with respect to the stimulator assembly 495 in the presence of substantially normal physical activities (e.g., walking, bathing, or the like) is substantially restricted.

When the fastening member 474 fastens the housing 465 to the remainder of the stimulator assembly 495, the protrusion 476 of the base 472 is received within the opening 469 of the receiving portion 466. The protrusion 476 is configured to limit movement of the stimulus generator 490 with respect to the housing 465 when the stimulus generator is received in the receiving portion 466 of the housing. In use, when the stimulator generator 490 is received in the receiving portion of the housing 465 and the protrusion 491 of the stimulus generator is received in the opening 469, the protrusion 476 of the base 472 engages a portion of the stimulus generator 490. For example, as illustrated in FIG. 39, the protrusion 476 engages a recess 492 defined by the stimulus generator 490 when the stimulus generator 490 is received in the receiving portion 466 of the housing 465. In some embodiments, the protrusion 476 is resiliently biased towards the portion of the stimulus generator 490. In this manner, the protrusion 476 retains the stimulus generator 490 with respect to the housing 465 when the stimulus generator 490 is received in the receiving portion 466 of the housing, and thus limits movement of the stimulus generator 490 with respect to the housing 465. Said another way, the resistance that occurs by engagement of the protrusion 476 with the portion of the stimulus generator 490 facilitates coupling of the stimulus generator 490 to the housing 465. The protrusion 476 is configured to release the stimulus generator 490 when the protrusion 476 is pushed, depressed, or otherwise moved by the operator (e.g., a physician or the patient).

Although the recess 492 is illustrated as being on an end of the stimulus generator 490 that is opposite to an end of the stimulus generator including the protrusion 491, in other embodiments, the recess (or other portion configured to engage protrusion 476) can be defined by a different portion of the stimulus generator.

When the stimulus generator 490 is received in the receiving portion 466 and the protrusion 491 of the stimulus generator is received in the opening 468, the stimulus generator 490 is electrically coupled to the battery 494. In some embodiments, the stimulus generator 490 is electrically coupled to the battery 494 via an electrical circuit 485 disposed on the substrate 480 in a similar manner as described above with reference to the portion of the stimulation system 370. The electrical circuit 485 includes at least one electrical pathway 487. More particularly, when the protrusion 491 of the stimulus generator is received in the opening 468, the

electrical contacts 493 are placed in contact with the electrical circuit 485. The battery 494 is also in electrical connection with the electrical circuit 485, as described above, and thus the battery 494 is placed in electrical communication with the stimulus generator 490. In other words, the electrical circuit 485 electrically couples the stimulus generator 490 to the battery 494. The electrical circuit 485 can also electrically couple the stimulus generator 490 to the electrode 497, as described above. The housing 465 is configured to substantially maintain the stimulus generator 490 in electrical communication with the electrical circuit 485 when the stimulus generator 490 is received in the receiving portion 466 and the housing 465 is disposed about at least a portion of the substrate 480 of the stimulator assembly 495.

A portion of the housing 465 is configured to form a substantially fluid-tight seal proximate to the receiving portion 466 when the at least a portion of the stimulus generator 490 is received in the receiving portion 466. In some embodiments, the housing 465 can form a seal to substantially prevent passage of a fluid from an area exterior to the housing and the stimulus generator 490 to an area interior to the housing 465 and/or an area between the housing 465 and the stimulus generator 490 (e.g. between a perimeter of the receiving portion 466 and the stimulus generator). In another example, the housing 465 can form a seal about the opening 468 when the protrusion 491 of the stimulus generator 490 is received in the opening to substantially prevent passage of a fluid there-through. The fluid can be, for example, a liquid, a slurry, a gas, or the like. Thus, the housing 465 and/or the stimulator assembly 495 can be characterized as being water-resistant.

The housing 465 can be constructed from any suitable material to provide the desired flexibility, sealing properties or the like. In some embodiments, the housing 465 can be constructed from a polymer or rubber compound having a modulus of elasticity and/or a flexural modulus of less than approximately 750,000 p.s.i. In some embodiments, the housing 465 can be constructed of an elastomer. The elastomer can be injection molded, e.g., from a bio-compatible material. In some embodiments, the elastomer has a mechanical elasticity of about 40 Shore D. Thus, the housing is soft and flexible, which facilitates compliance with a curvature of the patient's body and which facilitates accurate positioning of rigid parts of the stimulator assembly 495 (e.g., the battery 494, the stimulus generator 490) on the patient's body. For example, in some embodiments, the housing 465 exhibits a degree of flexibility that permits the housing 465 to be placed substantially about a surface of a radial body part of the patient (e.g., an arm, a leg, or other limb). Although the housing 465 is described herein as being constructed of an elastomer, in other embodiments, the housing 465 can be constructed of any suitable material, including, for example, a silicon, polyamide, or another suitable polymer, or any combination of the foregoing.

The housing 465 can be disposed on or coupled to the body of the patient in any suitable known manner. For example, the housing 465 can be coupled to the body using a medical plaster, which may be beneficial for larger bodily areas, including an abdomen or a backside of a shoulder. In another example, the housing 465 can be coupled to the body of the patient using a band, which may be beneficial for parts of the patient's body having a substantially circular cross-section (e.g., the arm, leg, or other limb). Use of the band also permits easy attachment, detachment, and repositioning of the housing 465 on the body of the patient.

In some embodiments, as illustrated in FIG. 52, a housing 190 can be configured to prevent migration and/or displacement of an electrode (e.g., a hydrogel electrode, not shown in

31

FIG. 52,) with respect to the housing in the presence of a shearing force and/or a mechanical stress. The housing 190 includes a flange 194 that extends from a body portion 196 of the housing to form a channel 198. In some embodiments, as illustrated in the cross-sectional view of the housing 190 shown in FIG. 52, the flange 194 forms a substantially continuous rim about a lower portion of the body portion 196 of the housing 190. In other embodiments, however, the housing can include a plurality of discrete flanges, which collectively form a discontinuous and/or non-contiguous rim about the lower portion of the body portion of the housing. For example, the housing can include two or more flanges disposed on the body portion at spaced (e.g., opposing) locations.

The channel 198 is configured to receive a portion of the periphery (or edge) of the electrode. In the embodiment illustrated in FIG. 52, the channel 198 is substantially U-shaped, however, in other embodiments, the channel can be any suitable shape for receiving a portion of the periphery of the electrode. When the peripheral portion of the electrode is received in the channel 198 of the flange 194, lateral movement of the electrode relative to the housing is restricted. In this manner, the housing 190 is configured to couple the electrode to the housing, and thus to a stimulator assembly (not shown in FIG. 52) to which the housing is attached.

Although the flange 194 and channel 198 have been illustrated and described herein as being integrally formed with the housing 190, in other embodiments, the electrode rim, or a portion thereof, can be manufactured as a separate and distinct portion that is couplable to the housing.

Further, although the housing 190 has been illustrated and described herein as including the electrode rim, in other embodiments, the electrode rim can be included in or coupled to a different portion of the stimulator assembly. For example, as illustrated in FIG. 53, a stimulator assembly 289 includes a rim 290, which is removably couplable to a base 246 of the stimulator assembly, as described herein. The rim 290 includes a body portion 296 and a flange 294. The flange 294 of the rim 290 is extended from the body portion 296 and forms a channel 298 between the flange and the body portion. The flange 294 is disposed about a portion of a periphery of at least one electrode 299 (e.g., a hydrogel electrode) such that a portion of the electrode's periphery 297 is received in the channel 298. In some embodiments, the electrode 299 is fixedly received in the channel 298 of the rim 290. In other embodiments, the electrode 299 is removably received in the channel 298 of the rim 290. The electrode 299 can be disposed within the channel 298 of the rim 290 during the manufacturing process, e.g., to permit distribution of the electrode and rim in a single package. As illustrated in FIG. 53, a protrusion 247 of the base 246 includes a recess 248 that is configured to receive a portion of the body portion 296 of the rim 290, and thus is configured to couple the rim 290 and electrode 299 to the base 246. As such, the rim 290 facilitates attachment, removal and/or replacement of the electrode 299 with respect to the stimulator assembly 289.

Although the rim 290 is shown and described above as being coupled to the base using recess 248 of the protrusion 247 of the base, in other embodiments, the rim 290 can be differently coupled to the base. For example, in some embodiments, the rim 290 can be coupled to the base with an elastic configured to be disposed about a portion of the base, a clip, a hook and loop fastener, or an adhesive, or any combination of the foregoing.

Further, in other embodiments, the electrode rim can be configured to be coupled to a different portion of a stimulator assembly, including, but not limited to, a substrate of the

32

stimulator assembly. In still other embodiments, an electrode rim can integrally formed with a base, substrate, or other suitable portion of a stimulator assembly.

FIGS. 43-47 illustrate a portion of a stimulation system 570 according to an embodiment. The portion of the stimulation system 570 is configured to deliver an electrical current from an electronic device (not shown) to a bodily tissue of a patient. The portion of the stimulation system 570 includes a substrate 580, a power source 594, a casing 592, electrodes 597, 599, an electrical circuit 585, a coupling member 572, and a housing 565, each of which are coupled to or otherwise disposed on the substrate 580.

The substrate 580 is flexible such that the substrate can substantially conform to the contours of the portion of the patient's body on which the portion of the stimulation system 570 is disposed. For example, the substrate 580 can be configured to be flexible such that the substrate conforms to the curvature of a patient's arm, leg, or back. In this manner, the substrate 580 is configured to facilitate positioning and placement of the stimulation system on the patient's body. In some embodiments, the substrate 580 can be similar to and/or constructed from similar materials as any of the substrates shown and described herein.

The substrate 580 has a first configuration and a second configuration different than the first configuration. In its first configuration, the substrate 580 has a first area (see, e.g., FIG. 45). Similarly stated, when the substrate 580 is in its first (or unfolded) configuration, the substrate 580 occupies a first surface area and/or defines a first "footprint." When the substrate 580 is in its first configuration, each of the electrodes 597, 599 and the electrical circuit 585 face a first direction and are disposed on a first side 581 of the substrate. For example, when the substrate 580 is in its first configuration and the substrate is positioned horizontally, the electrodes 597, 599 and the electrical circuit 585 can be characterized as facing "up."

In its second configuration, the substrate 580 has a second area less than the first area (see, e.g., FIGS. 46-47). Similarly stated, when the substrate 580 is in its second (or folded) configuration, the substrate 580 occupies a second surface area and/or defines a second "footprint" that is smaller than the first "footprint." When the substrate 580 is in its second configuration, the electrodes 597, 599 and at least a portion of the electrical circuit 585 each face a second direction different than the first direction, as illustrated in FIGS. 45-46. For example, when the substrate 580 is in its second configuration and the substrate is positioned horizontally, the electrodes 597, 599 and the portion of the electrical circuit 585 can be characterized as facing "down," or towards the bodily tissue, while the remaining portion of the electrical circuit remains facing "up," or away from the bodily tissue. The substrate 580 can be moved from its first configuration to its second configuration, for example, by folding under at least one of tab portion 596 or tab portion 598, as shown in FIGS. 46-47, respectively. Because the substrate 580 is flexible, the substrate is not damaged (e.g., cracked, broken, or creased) when the at least one of the tab portions 596, 598 is folded under. Because the electrodes 597, 599 and the electrical circuit 585 are formed on a first side 581 of the substrate 580, manufacturing of the substrate 580 is more easily accomplished. For example, in some embodiments, the electrodes 597, 599 and/or electrical circuit 585 can be formed by an electrically conductive ink printed onto the first side of the substrate 580.

As illustrated in FIG. 44, the power source 594 is coupled to the first side 581 of the substrate 580. The power source 594 can be any suitable source of power for providing power to the electronic device, including any source of power shown and

described herein. For example, the power source **594** can be a lithium battery, a rechargeable battery or the like. In some embodiments, the power source **594** provides enough power for approximately one week of standard use by a patient. In other embodiments, the power source **594** provides power for a longer period of time.

The casing **592** includes a rim **593** and defines a cavity (not shown, but indicated by arrow **595**). The power source **594** is received in the cavity **595** of the casing **592**. The rim **593** of the casing **592** is coupled to the substrate **580** to form a seal configured to substantially prevent the passage of moisture between the rim **593** of the casing **592** and the substrate **580**. In this manner, the casing **592** substantially prevents entry of moisture into the cavity **593**, and thus onto the power source **594** and/or the portion of the electrical circuit **585** coupled to the power source. As such, the casing **592** can limit a short-circuit of the power source **594** caused by exposure to moisture during the patient's daily activities, including bathing, perspiring, or swimming.

The electrical circuit **585** is configured to electrically couple each of the power source **594** and the electrodes **597**, **599** to the electronic device. Each electrode **597**, **599** is configured to contact a bodily tissue (either directly or via a secondary electrode), and to convey an electrical current between the electronic device and the bodily tissue. In some embodiments, at least one electrode **597**, **599** can be associated with a hydrogel electrode. For example, a hydrogel electrode can be bonded to the substrate surrounding the perimeter of the at least one electrode **597**, **599** such that the hydrogel electrode is disposed over and in electrical communication with the at least one electrode **597**, **599**.

The coupling member **572** is coupled to the flexible substrate **580**. More particularly, the coupling member **572** defines a first slot **571** and a second slot **573** different than the first slot. As illustrated in FIG. **43**, at least a first portion of the substrate **580** is disposed within the first slot **571**, and at least a second portion of the substrate is disposed within the second slot **573**. In some embodiments, the coupling member **572** is substantially rigid, and therefore provides support to the flexible substrate **580**. In some embodiments, the coupling member **572** can be similar in many respects to the base **372** described above with respect to the stimulation system **370**.

The coupling member **572** also includes a connective member **574** and a protrusion **576**. The substrate **580** is coupled to the connective member **574** such that a first portion **581'** of the first side **581** of the substrate **580** is non-parallel to a second portion **581"** of the first side of the substrate, as illustrated in FIG. **43**. A portion of the electrical circuit **585** is disposed on the second portion **581"** of the first side **581** of the substrate **580**. Thus, the portion of the electrical circuit **585** is disposed proximate to a portion of the electronic device when the electronic device is coupled to the stimulation system **570**, as described in more detail herein.

The coupling member **572** is configured to receive at least a portion of the electronic device in an area between the connective member **574** and the protrusion **576**. The protrusion **576** of the coupling member **572** is configured to releasably couple the electronic device to the substrate **580**. In some embodiments, the protrusion **576** is configured to releasably engage a recess of the electronic device (e.g., as shown and described above with respect to protrusion **476** and stimulus generator **490**).

The housing **565** can be similar in many respects to housing **465** described herein. The housing **565** is disposable over at least a portion of the substrate **580**. The housing includes a receiving portion **566** and defines an opening **569**. The receiving portion **566** is configured to receive at least a portion of the

electronic device. In some embodiments, the receiving portion **566** is defined by a surface **567** of the housing. The opening **569** of the housing **565** is configured to receive the protrusion **576** of the coupling member **572**. In this manner, the protrusion **576** is configured to releasably engage the recess of the electronic device when the electronic device is disposed in the receiving portion **566** of the housing **565**, and the protrusion **576** is received in the opening **569** defined by the housing.

In use, when the electronic device is received in the receiving portion **566** of the housing **565**, the electronic device is placed in electrical communication with the electrical circuit **585**. As such, the power source **594** can provide power to the electronic device such that the electronic device can generate an electrical current. The electrical current generated by the electronic device is transmitted from the electronic device to the electrical circuit **585**. The electrical current is then transmitted from the electrical circuit **585** to the electrodes **597**, **599**. The electrodes **597**, **599** convey the electrical current to the bodily tissue, thereby providing stimulation to the bodily tissue. In some embodiments, the electrodes **597**, **599** are also configured to receive the electrical current from the bodily tissue, and to transmit the electrical current to the electronic device via the electrical pathway. In some embodiments, the stimulation system **570**, or a portion thereof, is disposable. For example, the stimulation system **570** can be disposed of once the power source **594** is depleted and/or once the hydrogel electrode is no longer suitable for use (e.g., after approximately two weeks of continuous use). The usable life of the hydrogel electrode can be extended, however, if the electrode is stored properly when not in use (e.g., by applying a liner foil to the electrode to protect the hydrogel from humidity changes).

In some embodiments, however, the power source is removable and/or replaceable, for example when the power source is low or depleted after use. As illustrated in FIGS. **54-55**, a stimulator assembly **860** according to an embodiment is configured to transmit electrical stimulation to a body of a patient and includes a flexible housing **880**, a stimulus generator **862**, and a removable power source **870**.

The stimulus generator **862** can be similar in many respects to the stimulus generator **490**, described above. The housing **880** includes a first receiving portion **881**, which is configured to receive a portion of the stimulus generator **862**. The stimulus generator **862** can be removably coupled to the housing **880** in any suitable manner described herein. For example, the stimulus generator **862** can be coupled to the housing **880** when the portion of the stimulus generator **862** is received in the first receiving portion **881** and a protrusion **865** of a base (not shown) of the stimulator assembly **860** engages a recess **863** of the stimulus generator.

The housing **880** defines a second receiving portion **882**, which is configured to receive a portion of the power source **870**, different than the first receiving portion **881**. The receiving portions **881**, **882** can be similar in many respects to receiving portion **466** described above. For example, the second receiving portion **882** defines a first opening (not shown in FIGS. **54-55**) that is configured to receive a protrusion **874** of the power source **870**. The protrusion **874** of the power source **870** can include, for example, one or more electrical contacts configured to place the power source **870** in electrical communication with other portions the stimulator assembly **860** (e.g., the stimulus generator **862**, an electrical pathway, an electrode). The electrical contacts can be any suitable mechanism for electrically coupling the power source **870** with other portions the stimulator assembly **860**. In some embodiments, the electrical contacts are biased to help retain

35

the power source to the housing **880** and/or the stimulator assembly **860**. For example, the electrical contacts can include a spring, an elastomer, or other suitable biasing mechanism.

The second receiving portion **882** also defines a second opening (not shown in FIGS. **54-55**), which is configured to receive a protrusion **866** of a base **864** (shown in dashed lines in FIG. **54**) of the stimulator assembly **860**. The base **864** can be similar in many respects to the base **472**, base **372** and/or the base **172** shown and described above.

The protrusion **866** of the base **864** is configured to couple the power source **870** to the housing **880** and other components of the stimulator assembly **860**. Specifically, the protrusion **866** is configured to limit movement of the power source **870** with respect to the housing **880** when the power source is received in the receiving portion **882** of the housing. In use, when the power source **870** is received in the receiving portion of the housing **880** and the protrusion **874** of the power source is received in the first opening of the housing, the protrusion **866** of the base **864** engages a portion of the power source. For example, as illustrated in FIG. **54-55**, the protrusion **866** engages a recess **876** defined by the power source **870** when the power source is received in the receiving portion **882** of the housing **880**. In some embodiments, the protrusion **866** is resiliently biased towards the portion of the power source **870**. In this manner, the protrusion **866** retains the power source **870** with respect to the housing **880** when the power source is received in the receiving portion **882** of the housing, and thus limits movement of the power source with respect to the housing **880**. Said another way, the resistance that occurs by engagement of the protrusion **866** with the portion of the power source **870** facilitates coupling of the power source to the housing **880**. The protrusion **866** is configured to release the power source **870** when the protrusion **866** is pushed, depressed, or otherwise moved by the operator (e.g., a physician, patient, or other user). Although the recess **876** is illustrated as being on an end of the power source **870** that is opposite to an end of the power source including the protrusion **874**, in other embodiments, the recess (or other portion configured to engage protrusion **866**) can be defined by a different portion of the power source.

Because the power source **870** is removable the operator can remove the power source from the stimulator assembly **860**, for example, when the power source is depleted or otherwise insufficiently charged. After removal of the power source **870**, a replacement power source of similar construct can be coupled to the stimulator assembly **860**. In some embodiments, the power source **870** is also rechargeable. As such, at least a portion of the power source **870** is configured to be coupled to an external charging station, e.g., after removal from the stimulator assembly **860**. While the power source **870** is being recharged, a second power source of similar construct can be used with the stimulator assembly **860**, thus allowing for substantially uninterrupted treatment for the patient. Once the power source **870** is recharged to a sufficient power level and/or the secondary power source is depleted, the power source **870** can be re-coupled to the stimulator assembly **860**.

Because each of the power source **870** and the stimulus generator **862** are removably coupleable to the housing **880**, in some embodiments, the housing and/or other portions of the stimulator assembly **860** (e.g., an electrical pathway, an electrode) can be disposable. In this manner, the operator can selectively replace, for example, a used electrode coupled to the housing with another housing including an unused electrode. Also in this manner, manufacturing costs for the stimulator assembly **860** can be reduced because the power source

36

**870** and/or stimulus generator **860** are reusable instead of being disposed with the housing **880**. Furthermore, the power source **870** and stimulus generator **862** can be used with another stimulator assembly having a footprint (i.e., the configuration of a portion of the stimulator assembly facing a patient's body) that is different than a footprint of the stimulator assembly **860** and that includes a receiving portion configured to receive at least one of the power source and stimulus generator. As such, at least one of the power source **870** and stimulus generator **862** can be configured for use with a housing adapted to a specific anatomical location (e.g., a shoulder, a knee, a lower back).

When the power source **870** is received in the receiving portion **882** and the protrusion **874** of the power source is received in the first opening of the housing, the power source is electrically coupled to the stimulus generator **862**. In some embodiments, the power source **870** is electrically coupled to the stimulus generator **862** via an electrical pathway (not shown in FIGS. **54-55**) disposed on a substrate (not shown in FIGS. **54-55**) of the stimulator assembly **860** in a similar manner as shown and described above with reference to substrate **380**. More particularly, when the protrusion **874** of the power source **870** is received in the opening of the housing **880**, the electrical contacts are placed in contact with the electrical pathway. The stimulus generator **862** is also in electrical connection with the electrical pathway, and thus is placed in electrical communication with the power source **870**. In other words, the electrical pathway electrically couples the stimulus generator **862** to the power source **870**. The housing **880** is configured to substantially maintain the power source **870** in electrical communication with the electrical pathway when the power source is received in the receiving portion **882** and the housing **880** is disposed about at least a portion of the substrate of the stimulator assembly **860**. The housing **880** can be constructed of any suitable material, including those materials described above with respect to housing **465**.

In some embodiments, the power source **870** includes a battery (not shown) and a casing **871**. The battery is received in a cavity (not shown) of the casing **871**. The casing **871** can be configured to substantially prevent the passage of moisture between an area external to the casing **871** and the cavity of the casing. In this manner, the casing **871** substantially prevents entry of moisture into the cavity, and thus onto the battery. As such, the casing **871** can limit a short-circuit of the battery caused by exposure to moisture during the patient's daily activities, including bathing, perspiring, or swimming. The casing **871** also can help prevent inadvertent disconnection of the battery caused by friction that occurs during the patient's daily activities, including walking or dressing.

In some embodiments, the casing **871** includes a panel (not shown) movable between an open position, in which the cavity is accessible from an area external to the casing, and a closed position, in which the cavity is sealed and/or otherwise inaccessible from an area external to the casing. When the panel of the casing **871** is in its open position, the battery can be removed from and/or inserted into the cavity, e.g., to remove and/or replace a depleted battery. In some embodiments in which the power source **870** is rechargeable, at least one of the casing **871** or the battery is configured to be coupled to an external charging station. The battery can be any suitable source of power described herein, including as described above with respect to battery **394**.

Although the power source **870** has been illustrated and described herein as being coupled to the stimulator assembly **860** with protrusion **866** of the base **882**, in other embodiments, the power source can be coupled to the stimulator

assembly in a different manner, for example, as shown and described above with respect to apparatus 951.

Although stimulator system 570 and stimulator assembly 860 have been described herein as being wholly disposable or having a disposable housing, respectively, in other embodiments, a stimulator system can include a different disposable portion and/or reusable portion. Schematically illustrated in FIG. 56, a stimulator system 1000 according to an embodiment is configured to generate and transmit electrical stimulation through a bodily tissue of a patient. The stimulator system 1000 includes a stimulator assembly 1010 removably coupled to an electrode assembly 1040. Components of the stimulator system 1000 can be similar in many respects to components of apparatus shown and described herein (e.g., components of apparatus 100, 200, stimulation system 370, 570, stimulator assembly 495, 860). Referring to FIG. 56, the stimulator assembly 1010 includes a housing 1012, an electrical pathway 1014, a first connector assembly 1016, a stimulus generator 1020, and a power source 1030.

The stimulus generator 1020 is configured to generate the electrical stimulation. The stimulus generator 1020 can be similar in many respects to any stimulus generator described herein (e.g., external stimulator  $S_1$ - $S_{11}$ , stimulus generator 490, 862), except that the stimulus generator need not be configured to be external and/or removable. In other words, the stimulus generator 1020 can include internal components configured to generate the electrical stimulation similar to the internal components of any stimulus generator described herein, but need not have an external casing, generally, or an external casing that is removably coupleable to the housing, specifically. For example, in some embodiments, the stimulus generator 1020 includes various electronic components that collectively are configured to generate the electrical stimulation and that are collectively disposed within the housing 1012 (e.g., on a substrate, not shown). The stimulus generator 1020 is electrically coupled to the power source 1030 via the electrical pathway 1014. The stimulus generator 1020 is also electrically coupleable to the electrode assembly 1040 via the electrical pathway 1014 and via the first connector assembly 1016.

The power source 1030 is configured to provide power to the stimulus generator 1020 via the electrical pathway 1014. The power source 1030 is configured to be rechargeable. More specifically, in some embodiments, the power source 1030 is configured to be recharged when the power source is enclosed within the housing 1012. The power source 1030 is configured to be in electrical communication with an external charger (not shown in FIG. 56) by the electrical pathway 1014 and the first connector assembly 1016. The power source can be any suitable energy supplying source that may or may not be rechargeable. For example, in some embodiments, is a conventional disposable battery. In some embodiments, the power source is a rechargeable battery. Specifically, the power source can be a Li-polymer battery (e.g., a 500 mAh Li-polymer battery). In some embodiments, the power source is a rechargeable version of any suitable source of power described herein.

The power source 1030 is configured to provide power to the stimulus generator 1020 over a long duration of time, with recharging. For example, in some embodiments, the power source 1030 is configured to provide power to the stimulus generator 1020 over a period of at least six months of standard use by a patient, with recharging. In some embodiments, the power source 1030 is configured to provide power over a period of at least one year, with recharging. In some embodiments, the power source 1030 is configured to provide power over a period of about two years, with recharging. In other

embodiments, the power source 1030 is configured to provide power to the stimulus generator 1020 for a period of less than six months of standard use by the patient. For example, in some embodiments, the power source 1030 is configured to provide power to the stimulus generator 1020 over a period of about one month, with recharging. In another example, in some embodiments, the power source 1030 is configured to provide power over a period of about one week, with recharging.

The power source 1030 is configured to provide power to the stimulus generator 1020 for a shorter duration on a single charge (i.e., before being depleted to a level insufficient to power the stimulus generator 1020). For example, in some embodiments, the power source 1030 is configured to provide power for up to twelve hours on a single charge. In other embodiments, the power source 1030 is configured to provide power to the stimulus generator 1020 for at least twelve hours on a single charge. For example, in some embodiments, the power source 1030 is configured to provide power to the stimulus generator 1020 for at least twenty-four hours on a single charge. In another example, in some embodiments, the power source 1030 is configured to provide power for forty-eight or more hours on a single charge. In still another example, in some embodiments, the power source 1030 is configured to provide power for more three, four, or more days on a single charge. Although the stimulator assembly 1110 has been illustrated and described herein as including a permanent rechargeable power source 1130, in other embodiments, a stimulator assembly can include a replaceable power source (e.g., as described above with respect to power source 870).

The first connector assembly 1016 is configured to electrically couple the stimulator assembly 1010 to the electrode assembly 1040. As illustrated in FIG. 56, the first connector assembly 1016 is electrically coupled to the stimulus generator 1020 and the power source 1030. In some embodiments, the first connector assembly 1016 is configured to provide both a mechanical and an electrical connection between the stimulator assembly 1010 and the electrode assembly 1040. Said another way, when the stimulator assembly 1010 is mechanically coupled to the electrode assembly 1040 via the first connector assembly 1016, the stimulator assembly 1010 is also placed in electrical communication with the electrode assembly 1040. The first connector assembly 1016 can include any suitable mechanism for electrically and/or mechanically connecting the stimulator assembly 1010 to the electrode assembly 1040, including but not limited to, a snap-fit connector. In some embodiments, the first connector assembly 1016 includes a metal electrode. In some embodiments, the first connector assembly 1016 includes a conductive ink, a wire, or the like. In some embodiments, the first connector assembly 1016 is formed in a unique shape to ensure that only electrodes with a corresponding-shape connector (e.g., second connector assembly 1044, described below) can be coupled to the housing 1012. Such a configuration can also ensure that the housing 1012 is coupled to the electrode in a pre-determined orientation.

The first connector assembly 1016 is configured to electrically couple the power source 1030 to an external charger (not shown in FIG. 56). In some embodiments, the first connector assembly 1016 is configured to mechanically couple the power source 1030 to the external charger. In some embodiments, the first connector assembly 1016 is configured to both electrically and mechanically couple the power source 1030 to the external charger. The first connector assembly 1016 can include any suitable mechanism for electrically coupling the power source 1030 to the external charger, including, but not



limited to, a mechanism described above with respect to connections between the stimulator assembly 1010 and the electrode assembly 1040. In some embodiments, the first connector assembly 1016 includes at least a first connector (not shown) configured to electrically and/or mechanically couple the stimulator assembly 1010 to the electrode assembly 1040 and a second connector (not shown) different than the first connector and configured to electrically and/or mechanically couple the stimulator assembly to the external charger. In this manner, in some embodiments, the stimulator assembly 1010 is configured to be simultaneously connected to both the electrode assembly 1040 and the external charger.

In some embodiments, the stimulator assembly 1010 is configured to prevent generation and/or transmission of the electrical stimulation to the electrode assembly 1040 when the stimulation assembly is connected to the external charger. In some embodiments, for example, the first connector assembly 1016 is configured to only permit an electrical and/or mechanical connection between the power source 1030 and the external charger when the stimulator assembly 1010 is not electrically connected to the electrode assembly 1040. For example, a connector (not shown) of the first connector assembly 1016 can be configured for connection with each of the electrode assembly 1040 and the external charger such that when the connector is connected to one of the electrode assembly or the external charger it is prevented from being simultaneously connected to the other of the electrode assembly or the external charger. In other words, the connector is shared between the electrode assembly 1040 and the external charger. As such, when the connector of the first connection assembly 1016 is connected to the external charger, it is prevented from also being connected to the electrode assembly 1040. In other embodiments, the external charger is configured to physically interfere with a connection between the stimulator assembly 1010 and the electrode assembly 1040 when the external charger is connected to the stimulation assembly. In still other embodiments, the stimulator assembly 1010 can include additional hardware, software, or a combination thereof, configured to prevent simultaneous charging of the power source 1030 and transmission of the electrical stimulation to the electrode assembly 1040.

The first connector assembly 1016 is disposed proximate to a bottom portion 1013 of the housing 1012. In some embodiments, for example, the connector is substantially enclosed within a cavity 1015 of the housing 1012. In some embodiments, the first connector assembly 1016 is disposed on an outer surface of the bottom portion 1013 of the housing 1012, such that the first connector assembly is exterior to the cavity 1015 of the housing. In still other embodiments, a portion of the first connector assembly 1016 is enclosed within the cavity 1015 of the housing 1012 and another portion of the first connector assembly is exterior to the housing 1012.

The electrical pathway 1014 is configured to electrically couple the first connector assembly 1016 to the at least one of the stimulus generator 1020 and the power source 1030. In some embodiments, for example, the electrical pathway 1014 includes a wire configured to electrically connect the stimulus generator 1020 and the power source 1030. In some embodiments, a portion of the electrical pathway 1014 is a pathway of conductive ink printed onto a substrate (not shown in FIG. 56). The substrate can be, for example, any suitable substrate described herein (e.g., substrate 102, PCB 202, flexible substrate 380, 580). In another example, the substrate can be substantially rigid (e.g., have little to no compliance to a bodily curvature). In some embodiments, at least one of the electrical pathway 1014, the first connector assembly 1016,

the stimulus generator 1020, and the power source 1030, or any combination thereof, is coupled to the substrate.

The housing 1012 is configured to at least partially enclose components of the stimulator assembly 1010, such as, but not limited to, the stimulus generator 1020, the power source 1030, the electrical pathway 1014, the first connector assembly 1016, the substrate, or the like. In this manner, the housing 1012 is configured to protect the enclosed components from external contaminants, including, for example, exposure to dirt, moisture, fluids, and the like. In some embodiments, the housing 1012 defines an opening (not shown in FIG. 56) configured to provide access to a portion of the first connector assembly 1016. In some embodiments, such as when at least a portion of the first connector assembly 1016 is external to the housing 1012 cavity 1015, the housing is disposed about the portion of the first connector assembly in such a manner as to provide a seal between the cavity and an area exterior to the cavity.

The housing 1012 is configured to be durable (e.g., by being constructed of durable materials). For example, the housing 1012 is configured to withstand being bumped, exposed to moisture (e.g., humidity, sweat), and the like that occur during normal daily activities (e.g., walking, shopping). It is desirable that the housing 1012, and the stimulator assembly 1010 generally, be configured for use in normal daily activities by a patient for a period of about two years. The housing 1012 can be constructed of any suitable material, including, but not limited to, any suitable material, or combination of materials, described herein (e.g., with respect to housing 465).

In some embodiments, the stimulator assembly 1010 is configured to alert the user when the power source 1030 has been depleted to a threshold level. For example, in some embodiments, the stimulator assembly 1010 is configured to provide an audible alert (e.g., a beep, a recorded verbal warning), a tactile alert (e.g., a vibration), a visual alert (e.g., a light or other visual indicia), or a combination thereof, when the power source 1030 has been depleted to the threshold level. In some embodiments, the stimulator assembly 1010 is programmable, for example, so that the threshold level can be set by an operator (e.g., a physician, the patient, etc.).

The electrode assembly 1040 of the stimulator system 1000 is removably coupleable to the stimulator assembly 1010, as shown in FIGS. 56-57. In some embodiments, the electrode assembly 1040 is configured to be coupled to the housing 1012 proximate to the bottom portion 1013 of the housing. The electrode assembly 1040 includes at least one electrode 1042 and a second connector assembly 1044. In some embodiments, the second connector assembly 1044 of the electrode assembly 1040 is configured to be mechanically and/or electrically coupled to the first connector assembly 1016 of the stimulator assembly 1010. In some embodiments, the second connector assembly 1044 is configured to provide both a mechanical and an electrical connection between the electrode assembly 1040 and the stimulator assembly 1010. The second connector assembly 1044 can include any suitable mechanism for electrically and/or mechanically connecting the stimulator assembly 1010 to the electrode assembly 1040. For example, the first connector assembly 1016 and the second connector assembly 1044 can include complementary (or mating) connectors (e.g., snap-fit connectors). In some embodiments, the second connector assembly 1044 includes a metal electrode. In some embodiments, the second connector assembly 1044 includes a conductive ink, a wire, or the like.

The electrode assembly 1040 is configured to receive the electrical stimulation from the stimulator assembly 1010 via



41

the coupled connector assemblies **1016**, **1044**. The second connector assembly **1044** is configured to transmit the electrical stimulation to the electrode **1042**. The electrode **1042** is configured to facilitate transmission of the electrical stimulation through the bodily tissue. The electrode **1042** is configured to contact bodily tissue. For example, in some embodiments, the electrode assembly **1040** includes a hydrogel electrode configured to adhere to the patient's skin. The electrode assembly **1040** can remain in contact with (or adhered to) the bodily tissue when the stimulator assembly **1010** is decoupled from the electrode assembly **1040**.

The electrode assembly **1040** is disposable. For example, the electrode assembly **1040** can be disposed of once the electrode is no longer suitable for use (e.g., after approximately two weeks of continuous use). In use, the electrode assembly **1040** is decoupled from the stimulator assembly **1010** before being discarded. In this manner, the stimulator assembly **1010** can continue to be used with a replacement electrode assembly.

The electrode assembly **1040** can be of any desired shape, size, or footprint. For example, in some embodiments, the electrode assembly is configured to be positioned at a specific anatomical location, such as a lower back (FIG. **58A**), a shoulder (FIG. **58B**), an elbow (FIG. **58C**), or a knee (FIG. **58D**). In this manner, the electrode assembly **1040** is configured to comply with bodily curvature, which may facilitate adhesion of the electrode **1042** to the bodily tissue. As such, the electrode assembly **1040** may help eliminate the need for sleeves to maintain the assembly adjacent the desired bodily tissue. In some embodiments, the footprint of the electrode assembly **1040** is determined by a shape, size, or footprint of the electrode **1042**.

Although the electrode assembly **1040** has been illustrated and described herein as being configured to adhere to the bodily tissue, in some embodiments, a stimulation system includes an electrode assembly configured to be coupled to the bodily tissue in another manner. In some embodiments, a stimulation system includes an electrode assembly configured to be coupled to the bodily tissue by a garment. The garment is configured to maintain the electrode assembly at a desired position with respect to the bodily tissue. In some embodiments, the garment is configured to be securely wrapped about a portion of the stimulation system (e.g., the electrode assembly, a stimulation assembly, or both the electrode and stimulation assemblies). For example, in use, the electrode assembly can be disposed at the desired position with respect to the bodily tissue and then garment can be securely wrapped about the electrode assembly (and, optionally, about a portion of the patient's body) to couple the electrode assembly to the bodily tissue. The garment can define an opening, for example, to permit access to a connector assembly of the electrode assembly. In this manner, a stimulator assembly of the stimulation system can be coupled to the electrode assembly when the electrode assembly is coupled to the bodily tissue using the garment. In another example, the stimulator assembly and electrode assembly can be coupled together and disposed at the desired position with respect to the bodily tissue, and the garment can be disposed about the coupled stimulator and electrode assemblies so that the electrode assembly is coupled to the bodily tissue.

In some embodiments, the garment includes at least a portion of the stimulation system. For example, in some embodiments, an electrode assembly is included in the garment. As such, when the garment is donned by the patient, the electrode assembly is also donned by the patient. In some embodiments, the garment is configured to align the electrode assembly at the desired position with respect to the bodily

42

tissue. The garment can be, for example, a sleeve, a strap, a belt, a vest, or the like. In other embodiments, an electrode assembly is coupled to a bodily tissue using a combination of an adhesive and a garment.

In some embodiments, as illustrated in FIGS. **59-61**, a stimulator system **1100** according to an embodiment is configured for use with an electrical lead implanted into the patient's bodily tissue **T**. The stimulator system **1100** and its components can be similar in many respects to stimulator system **1000** and its respective components, described in detail above. The stimulator system **1100** includes a stimulator assembly **1110** (FIG. **59**) and a disposable electrode assembly **1140** (FIG. **60**). The stimulator assembly **1110** includes a housing **1112**, a stimulus generator **1120** (shown in dashed lines in FIG. **59**), a power source **1130** (shown in dashed lines in FIG. **59**), an electrical pathway (not shown), and a first connector assembly (not shown). The stimulator assembly **1110** and its components can be similar in many respects to stimulator assembly **1010** and its components, described above. The stimulator assembly **1110** is removably couplable to the electrode assembly **1140**. Specifically, the electrode assembly **1140** includes a second connector assembly **1144** removably couplable to the first connector assembly of the stimulator assembly **1110**. The second connector assembly **1144** includes a first connector **1145** and a second connector **1147**. Each of the connectors **1145**, **1147** is configured to be received by the first connector assembly. The electrode assembly **1140** includes a first electrode **1142** and a second electrode **1143**. The electrodes **1142**, **1143** can be any suitable electrode described herein (e.g., electrode **1042**).

As illustrated in FIG. **61**, each of the first electrode **1142** and the second electrode **1143** is configured to contact the bodily tissue **T** and to facilitate transmission of an electrical stimulation **E** through the bodily tissue, for example through subcutaneous bodily tissue located below and/or between the first electrode and the second electrode. The first electrode **1142** is configured to facilitate transmission of the electrical stimulation **E** from the stimulator assembly **1110** through the bodily tissue **T**. The first electrode **1142** can facilitate transmission of the electrical stimulation **E** to an electrical lead **L** at least partially implanted within the bodily tissue, as illustrated in FIG. **61**. For example, in some embodiments, the first electrode **1142** is a cathode configured to help transmit the electrical stimulation to a receiver (or pick-up) end of the electrical lead **L**. The second electrode **1143** is configured to receive at least a portion of the electrical stimulation **E**. As illustrated in FIG. **61**, for example, the second electrode **1143** can receive electrical stimulation **E** that has passed through the bodily tissue **T** and/or through the electrical lead **L** at least partially implanted within the bodily tissue. For example, in some embodiments, the second electrode **1143** is an anode configured to receive at least a portion of the electrical stimulation **E** from a stimulating end of the electrical lead **L**. In this manner, the stimulator system **1100** is configured to reduce loss of the electrical stimulation within the bodily tissue when the system is used with the implanted lead. Specifically, because the electrodes **1142**, **1143** are positionable over the pick-up end and stimulating end, respectively, of the electrical lead **L**, the electrode assembly **1140** is configured to increase a pick-up ratio of the electrical current **C** as compared to an electrode assembly with a smaller footprint preventing the electrodes from being positioned proximate to ends of the electrical lead.

The electrodes **1142**, **1143** are configured to adhere to bodily tissue (e.g., the skin) of the patient. Each electrode **1142**, **1143** of the electrode assembly **1140** includes a gel on the tissue-facing surface of the electrode. The gel can be any

suitable known gel including, but not limited to, wet gels, karaya-gum-based hydrogels, and/or synthetic copolymer-based hydrogels. The first electrode **1142** and second electrode **1143** can be, for example, a cathodic gel electrode and an anodic gel electrode, respectively. Although the electrode assembly **1140** has been illustrated and described herein as including two electrodes **1142**, **1143**, in other embodiments, an electrode assembly can include any suitable number of electrodes. For example, an electrode assembly can include three, four, or more electrodes.

Although the electrode assembly **1140** has been illustrated and described herein as including a connector assembly **1144** and two electrodes **1142**, **1143**, in other embodiments, an electrode assembly can include additional components. For example, in some embodiments, an electrode assembly includes a support portion. The support portion can be configured to provide additional structural support or reinforcement, for example, to a portion of the electrode(s). In another example, the support portion can be configured to facilitate coupling of the electrode assembly to the stimulator assembly. In yet another example, an electrode assembly can include a tab configured to held by a user to facilitate removal of the electrode assembly from the bodily tissue.

Although the stimulus generator **1120** and the power source **1130** have been illustrated and described as being spaced apart within the stimulator assembly, in other embodiments, a stimulator assembly can include a stimulus generator and a power source disposed in another configuration. For example, in some embodiments, a stimulator assembly can include a stimulus generator that is disposed in a stacked configuration on top of the power source, or vice versa. In another example, in some embodiments, a stimulator assembly can include a stimulus generator and a power source that are disposed in close proximity to each other (e.g., side by side within the housing). Any suitable design configuration of the stimulus generator and power source may be used. In this manner, the stimulator assembly can have a more compact configuration.

In use, the stimulator system **1100** is disposed on the target bodily tissue and stimulation of the bodily tissue is initiated by the operator. The stimulator assembly **1110** can be removed from the electrode assembly **1140** for bathing, swimming, or other activity, however the electrode assembly can remain disposed on (or adhered to) the bodily tissue. Following the activity, the stimulator assembly **1110** is reattached to the electrode assembly **1140** and selective stimulation of the bodily tissue can be resumed. The stimulator assembly **1110** is generally removed from the electrode assembly **1140** and recharged daily using the external charger. After recharging, the stimulator assembly is reattached to the electrode assembly **1140**. The electrode assembly **1140** can be replaced on a weekly basis, or as needed. The stimulator assembly **1110** can be replaced annually, bi-annually, or as needed, for example, when the power source **1130** will no longer maintain a charge sufficient for powering the stimulus generator **1120** for a desired period of time.

FIG. **48** is a flow chart of a method **670** of assembling a portion of a stimulator assembly according to an embodiment. The method includes folding a tab portion of a flexible substrate such that the tab portion of the flexible substrate is in contact with a bottom side of a body portion of the flexible substrate and such that an electrical circuit formed on a top side of the flexible substrate extends about an edge of the fold, **675**. The flexible substrate can be any substrate of the types shown and described herein (e.g., PCB **202**, PCB **792**, substrate **380**, substrate **480**, substrate **580**). In some embodiments, the tab portion of the flexible substrate is bonded to the

bottom side of the body portion of the flexible substrate. The electrical circuit can be formed on the top side of the flexible substrate in any manner shown and described herein. For example, the electrical circuit can be printed on the substrate. In another example, the electrical circuit can be partially embedded in the substrate such that a portion of the electrical circuit is exposed on a surface of the substrate.

In some embodiments, the method optionally includes coupling a portion of the flexible substrate to a rigid base, **680**. The base can be, for example, any of the bases shown and described herein (e.g., base **372**). The flexible substrate can be coupled to the rigid base in any suitable manner. In some embodiments, for example, at least a portion of the flexible substrate is woven through one or more openings defined by the rigid base (e.g., similar to the coupling of substrate **380** and base **372** shown and described above). The flexible substrate can, for example, be woven through a set of slots defined by the base.

In some embodiments, the method optionally includes disposing a first portion of the flexible substrate that includes the electrical circuit over a protrusion of the rigid base such that the first portion of the flexible substrate is non-parallel to a second portion of the flexible substrate, **685**. For example, in some embodiments, the flexible substrate is disposed over the protrusion of the base similar to the disposal of substrate **380** over the protrusion **374** of the base **372** as shown and described above.

In some embodiments, the method optionally includes folding a second tab portion of the flexible substrate such that the second tab portion of the flexible substrate is in contact with the bottom side of the body portion of the flexible substrate and such that the electrical circuit extends about an edge of the fold of the second tab portion, **690**. For example, in some embodiments, the second tab of the flexible substrate can be folded such that the substrate is in the second configuration as illustrated in FIGS. **45-47** and described above with respect to substrate **580**.

Although the method **670** of assembling a portion of a stimulator assembly has been illustrated and described in one order, the activities can occur in a different order. For example, in some embodiments, the substrate is coupled to the rigid base prior to folding the tab portion of the flexible substrate. Furthermore, each activity is not required for assembling the portion of the stimulator assembly. For example, in some embodiments, a portion of the electrical circuit can be disposed on the top and bottom side of the second tab portion, wherein the second tab portion need not be folded to extend the electrical circuit about an edge of the fold of the second tab portion. Additionally, certain of the events may be performed concurrently in a parallel process when possible.

While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made. For example, although the apparatus have been shown and described above as including a certain number of electrodes, in other embodiments, any suitable number of electrodes can be included. Further, elements of each embodiment described herein may be combined in any suitable manner with one or more elements of another embodiment described herein. For example, a hydrogel electrode may be selectively used with any of the foregoing apparatus, regardless if an embodiment was specifically described as including a hydrogel electrode. In another example, where an apparatus is shown and described herein as including a mechanical connector for

45

connection to an external stimulator, in other embodiments, the apparatus can include a wireless connector for connection to the external stimulator.

Although various embodiments have been described as having particular features and/or combinations of components, other embodiments are possible having a combination of any features and/or components from any of the embodiments as discussed above. For example, a stimulation system according to an embodiment can include a base similar to the base **372** as described above and a folded substrate similar to the substrate **580** as described above.

Thus, the breadth and scope of the invention should not be limited by any of the above-described embodiments, but should be defined only in accordance with the following claims and their equivalents. The previous description of the embodiments is provided to enable any person skilled in the art to make or use the invention. While the invention has been particularly shown and described with reference to embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

An experiment was performed utilizing a first apparatus **990** and a second apparatus **991** according to an embodiment of the invention, as illustrated in FIG. **49**, to estimate the leakage current when each of the first apparatus and the second apparatus is immersed in solutions encountered during daily activities. Apparatus **990** includes a first metal connector **992** and a second metal connector **994**. Apparatus **991** was cut in the middle and the cut was filled with hot glue **997** to increase impedance between a first metal connector **993** and a second metal connector **995**, as illustrated in FIGS. **49** and **50**. Impedance of both direct current (DC) and alternating current (AC) was measured between the two metal connectors **992**, **994** of the first apparatus **990**. Impedance of both DC and AC was measured between the two metal connectors **993**, **995** of the second apparatus **991** prior to submersion in the liquid. AC impedance was measured between the two metal connectors **992**, **994** of the first apparatus **990** while the first apparatus was attached to skin of a patient. AC impedance was measured between the two metal connectors **993**, **995** of the second apparatus **991** while the second apparatus was attached to the skin of the patient.

Each of the first apparatus **990** and the second apparatus **991** was submerged in a liquid with a 3V Lithium coin battery attached to its respective metal connectors, as illustrated in FIG. **51** with reference to apparatus **991**. The discharge current and voltage were each measured for each apparatus **990**, **991** when the apparatus was submerged. Each of the discharge current, voltage and impedance were measured after removing the each apparatus **990**, **991** from its respective liquid submersion. Additionally, each of the discharge current, voltage and impedance were measured after slight wiping of the each apparatus **990**, **991**. Each apparatus **990**, **991** was then washed with tap water. These steps were performed for each of the following liquids: tap water, hot tub water, and saline solution. The discharge current showed an expected battery discharge, while AC impedance may represent leakage of the stimulation current on the patch rather than through bodily tissue. All AC impedance measurements were performed at 1 KHz. The results are shown in Table 1, below.

46

TABLE 1

Effects of Various Liquids on the Apparatus*				
	Apparatus 990		Apparatus 991	
	Battery current	Impedance	Battery leakage	Impedance
Submersion in tap water	1.5 mA		1.6 mA	
Removal from tap water	0.6 mA	2.0 Kohm	0.1 mA	$\infty$ Kohm
After wiping	0.3 mA	27 nF	>0.1 mA	49 pF
		300 Kohm		$\infty$ Kohm
		2.0 nF		30 pF
Submersion in hot tub water	2 mA		2.2 mA	
Removal from hot tub water	0.8 mA	2.0 Kohm	0.07 mA	1.7 Kohm
After wiping	0.5 mA	13 nF	>0.01 mA	1.2 nF
		90 Kohm		230 Kohm
		1.0 nF		128 pF
		(130 Kohm after absorbing water with napkin)		
Submersion in saline solution	9 mA		10 mA	
Removal from saline solution	0.4 mA	0.34 Kohm	0.04 mA	3.5 Kohm
After wiping	0.3 mA	212 nF	>0.01 mA	1.7 nF
		0.5 Kohm		230 Kohm
		134 nF		94 nF

\*Before submersion, DC impedance approached infinity; AC impedance R approached infinity, C = pF; Impedance on the skin (AC) R = 8.3 Kohm, C = 36 nF. Battery voltage (when connected to the immersed patch) was 2.8-2.9 v.

The results indicate that daily use of a bath or hot tub for 20 minutes drains 0.5-0.7 mAh per use (or 3.5-4.9 mAh per week). Assuming that the apparatus **991** incorporates a power source similar to a cr2032 coin lithium battery (225 mAh capacity), this drain is insignificant. A daily swim in ocean water for 20 minutes will drain ~3.3 mAh per day (or ~21 mAh per week), which is insignificant when compared to the suggested power source capacity. Further, the current drain during the drying period of 1 hour (for apparatus **990**) is less than 1 mA per use (7 mAh per week) and does not add significant discharge compared with the power source capacity. After removal from the liquid, apparatus **991**, which has a hydrophobic plastic barrier (similar to barrier **218** described above) ensures significantly lower power source discharge current compared to apparatus **990**, which lacks a barrier. A significant amount of electrical current escapes via apparatus **990** and would not be expected to reach the body when apparatus **990** is exposed to liquid. However, apparatus **991** would be expected to divert most of the electrical current to the body, if wiped.

What is claimed is:

1. An apparatus, comprising:

a rigid base having a protrusion, the base configured to be coupled to an electronic device; and

a flexible substrate having a first surface and a second surface and including an electrical circuit configured to electronically couple the electronic device to an antenna, the antenna coupled directly to the flexible substrate, the flexible substrate coupled to the base such that a first portion of the second surface is in contact with the protrusion, a second portion of the second surface is non-parallel to the first portion.

2. The apparatus of claim 1, wherein at least a first portion of the flexible substrate is disposed within a first slot defined by the base, at least a second portion of the flexible substrate is disposed within a second slot defined by the base, the first slot different than the second slot.

47

3. The apparatus of claim 1, wherein the base defines a plurality of slots, each slot of the plurality of slots configured to receive a portion of the flexible substrate.

4. The apparatus of claim 1, wherein:

a first portion of the first surface of the flexible substrate includes at least a portion of the electrical circuit, the portion of the electrical circuit configured to be in electrical communication with an electrical contact disposed on a first portion of the electronic device; and

the base includes a second protrusion configured to engage a second portion of the electronic device when the electronic device is coupled to the base, the second portion of the electronic device different than the first portion of the electronic device.

5. The apparatus of claim 1, further comprising:

a hydrogel electrode coupled to the second surface of the substrate, the substrate further including a conductive region electrically coupled to the electrical circuit and a plurality of non-conductive regions configured to facilitate retention of the hydrogel electrode with respect to the second surface of the substrate.

6. An apparatus, comprising:

a flexible housing configured to be disposed about at least a portion of a stimulator assembly, the stimulator assembly including at least a battery, an electrode, and a stimulus generator, the housing including a receiving portion configured to receive at least a portion of the stimulus generator, the receiving portion defining a first opening configured to receive a protrusion of the stimulus generator when the stimulus generator is received in the receiving portion such that the stimulus generator is electrically coupled to the battery, the receiving portion defining a second opening different than the first opening, the second opening configured to receive a protrusion of a base of the stimulator assembly such that the protrusion can limit movement of the stimulus generator with respect to the housing when the stimulus generator is received in the receiving portion of the housing.

7. The apparatus of claim 6, wherein a portion of the housing is configured to form a substantially fluid-tight seal proximate to the receiving portion when at least the portion of the stimulus generator is received in the receiving portion.

8. The apparatus of claim 6, wherein the housing defines a recess configured to receive a fastening member of the stimulator assembly, the fastening member configured to limit movement of the housing relative to the stimulator assembly when the housing is disposed about the portion of the stimulator assembly and the fastening member is received in the recess.

9. The apparatus of claim 6, wherein the housing is configured to substantially maintain the stimulus generator in electrical communication with an electrical pathway coupled to a substrate of the stimulator assembly when the stimulus generator is received in the receiving portion, the electrical pathway electrically couples the stimulus generator to at least one of the electrode or the battery.

10. A method, comprising the steps of:

folding a tab portion of a flexible substrate such that the tab portion of the flexible substrate is in contact with a bottom side of a body portion of the flexible substrate and such that an electrical circuit formed on a top side of

48

the flexible substrate extends about an edge of the fold, the flexible substrate configured to be coupled to a body.

11. The method of claim 10, further comprising:

coupling at least a portion of the flexible substrate to a rigid base.

12. The method of claim 10, further comprising:

disposing a first portion of the flexible substrate including the electrical circuit over a protrusion of a rigid base such that the first portion of the flexible substrate is non-parallel to a second portion of the flexible substrate.

13. The method of claim 10, further comprising:

weaving at least a portion of the flexible substrate through a slot defined by a rigid base.

14. The method of claim 10, wherein the tab portion is a first tab portion, further comprising:

folding a second tab portion of the flexible substrate such that the second tab portion of the flexible substrate is in contact with the bottom side of the body portion of the flexible substrate and such that the electrical circuit extends about an edge of the fold of the second tab portion.

15. An apparatus, comprising:

a hydrogel electrode; and

a substrate including a lower surface, a conductive region, and a plurality of discrete non-conductive regions, the conductive region electrically coupled to an electrical circuit of the substrate and to the hydrogel electrode, the plurality of discrete non-conductive regions configured to facilitate coupling of the hydrogel electrode with the lower surface of the substrate, at least one non-conductive region of the plurality of discrete non-conductive regions extending beyond a surface of the conductive region.

16. An apparatus, comprising:

a hydrogel electrode; and

a substrate including a lower surface, a conductive region, and a plurality of discrete non-conductive regions, the conductive region electrically coupled to an electrical circuit of the substrate and to the hydrogel electrode, the plurality of discrete non-conductive regions configured to facilitate coupling of the hydrogel electrode with the lower surface of the substrate, at least one non-conductive region of the plurality of discrete non-conductive regions is at least one of (1) a solder mask, (2) a cavity formed in a surface of the conductive region, or (3) formed by a coating applied to a surface of the conductive region.

17. The apparatus of claim 16, wherein at least one non-conductive region of the plurality of discrete non-conductive regions is formed by a coating applied to the surface of the conductive region.

18. The apparatus of claim 16, wherein at least one non-conductive region of the plurality of discrete non-conductive regions is a cavity formed in a surface of the conductive region.

19. The apparatus of claim 16, wherein at least one non-conductive region of the plurality of discrete non-conductive regions is a solder mask.

20. The apparatus of claim 1, wherein the electrical circuit is configured to electronically couple the electronic device to at least one of an electrode or a battery.

\* \* \* \* \*